IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION AT CLEVELAND

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	Case No. 1:17-md-2804
CASE TRACK THREE	**VOLUME 19** JURY TRIAL *(Pages 4765 - 5048)*
	October 29, 2021

TRANSCRIPT OF JURY TRIAL PROCEEDINGS

HELD BEFORE THE HONORABLE DAN AARON POLSTER

SENIOR UNITED STATES DISTRICT JUDGE

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I N D E X

(In open court at 8:48 a.m.)

THE COURT: All right. Everyone can be seated.

Okay. Everyone can be seated.

Okay. Do we have the exhibits for Mr. Pavlich and -- I guess he's the only one we have. Okay.

Any exhibits from either side with him?

MR. SWANSON: I'm sorry, Your Honor, for Pavlich, Your Honor?

THE COURT: Pavlich.

MR. SWANSON: Yeah, Brian Swanson for the Walgreens.

We admitted just -- or moved in just one exhibit. It's WAG-MDL-0111A, and I believe that's in without objection.

MR. WEINBERGER: No objection, Your Honor.

THE COURT: Okay. That's in without objection.

Were the plaintiffs offering any with him?

MR. WEINBERGER: No, Your Honor.

THE COURT: Okay. That's easy enough.

Okay.

MR. WEINBERGER: We're going to offer a photograph of the basement of his house.

MR. SWANSON: We object to the Steelers garbage can, Your Honor.

MR. WEINBERGER: I don't know if you noticed but he had a Pittsburgh Steeler flag in the background.

THE COURT: I was focusing on his treadmill but I didn't look at the trash can.

08:49:35 MR. LANIER: All I know is my daughter said she was glad the defense lawyer was there. It made her feel safer.

THE COURT: We'll see what the jurors are wearing today. If they kept their sweatshirts and things

08:49:46 from last Thursday night.

MR. MAJORAS: Your Honor, John Majoras. I have an issue to raise whenever you're done with --

THE COURT: Okay. I was going to raise some, but go ahead, Mr. Majoras.

08:49:55 MR. MAJORAS: May I approach to hand up an exhibit?

THE COURT: Sure.

MR. MAJORAS: Plaintiffs' 2848.

MR. WEINBERGER: Which one is that?

08:50:13 MR. MAJORAS: Your Honor, I've handed up Plaintiffs' Exhibit 2848. I will hand one to Mr. Lanier. These are actually documents -- part of a document -- set of exhibits that were given to us last night. This is as -- it's pretty plain, actually an appeal of a divorce

08:50:33 proceeding between --

MR. LANIER: Your Honor, we're not using this. Your Honor, Mark Lanier. We're not using this. We don't need to waste your time.

MR. MAJORAS: Your Honor, it's just outrageous that we even had to receive this. And I'm looking at this this morning and having a debate how I might have to handle it with this witness.

MR. LANIER: I didn't know anything about it, Judge. I won't use this.

08:50:47 THE COURT: Hold it. Let's slow down. One person at a time speak.

MR. MAJORAS: So if I may finish, Your Honor. This document is apparent on its face. It's only a 2-page document. It's a court proceeding. If you look -- although the name Robert Wailes is at the top, if you look the second paragraph on the bottom talks about a husband is a 46-year-old in good health, a CPA working for a national accounting firm. This is in Alabama.

Clearly there are some allegations in this particular divorce, which has nothing to do with this witness that in any case would not have been admissible or useful, but the fact we're getting this the night before while a witness is on the stand I believe is an outrage use of a document like this.

08:51:30 MR. LANIER: Judge, Mark Lanier here.

A, I know nothing about this. B, I'll represent to the Court Pete knows nothing about this. C, we'll find out who among the abundance of lawyers that work on this MDL may have done this and I'll have a talk with them.

08:51:49 But I have no intention of using anything like this and would never use anything like this. This is outrageous. And if Mr. Majoras would have come to me with it, we could have ended it without even taking the Court's time.

MR. MAJORAS: I saw it 15 minutes ago, or

08:52:03 15 minutes before I arrived here, Your Honor.

THE COURT: All right. Well, look, this was inappropriate. It wouldn't have been. . . -- it has to do with some other Robert Wailes. Candidly, even if it had been this Dr. Wailes, I don't think it would have been

08:52:18 admissible and it's -- I don't know if it's some sort of a joke, but --

MR. LANIER: I -- I --

THE COURT: Well, I'm actually more troubled --

08:52:26 I mean, Mr. Lanier, Mr. Weinberger, I -- no -- no one should be handing documents or things to defense and vice versa that you don't know about. I'm actually more troubled by that.

MR. LANIER: And I am as well, Your Honor.

08:52:44 THE COURT: Then someone --

MR. LANIER: And I am as well.

THE COURT: Someone gave it to them. It didn't come out of the ceiling.

MR. LANIER: And will find out, Your Honor, and we will deal with it internally.

08:52:53

THE COURT: No more -- no more -- because if it's given to them or they give something to you, the presumption is that either side is planning to use it at some point. Otherwise, you know, why would you give it? Why would you give it?

08:53:06

I would feel the same way if I were Mr. Majoras.

MR. LANIER: Yeah, and candidly, when he handed me the document just now, I didn't realize it was a different Robert Wailes. When I was standing up saying --

08:53:16

THE COURT: Well, right.

MR. LANIER: -- I won't use it, I wouldn't have used it if it was the right Robert Wailes. That's not a proper use, and I'm not that kind of lawyer, and I would not have done that. But I will chase down how this happened and I will take care of it internally.

08:53:28

THE COURT: I don't want any more things like that.

All right.

MR. MAJORAS: Thank you, Your Honor.

THE COURT: I have been sort of looking

08:53:37

forward to the schedule for the remainder of the trial and figuring out the best way to conclude it efficiently. If everyone uses all of their hours, remaining hours, we will -- we'll conclude this trial on Wednesday, November 10th.

08:54:01

Now, everyone may not use all their hours, but if they do, that's what -- we'll end on Wednesday the 10th. There's going to be no court on Thursday the 11th because that's Veteran's Day. Unless there's a strong consensus to the contrary, I don't think it's -- it's ideal to do final arguments and jury instructions on Friday, finish at about 5 or 5:30 on Friday.

08:54:22

Now, you know, the jury may decide they want to deliberate Friday night and all weekend. I mean, I don't set their rules. I mean, I set them when we're in trial. Once they deliberate, they decide when they start and when they leave. There's only one rule, they don't start deliberating until everyone's there, but they set hours. But typically it's been my experience that jurors tend to keep roughly the same hours that they've been keeping. So they're likely to want to break for the weekend and -- without doing much deliberating, so I -- unless everyone feels strongly to the contrary, I would just give everyone Friday off, you could prepare your final arguments, and then we would charge the jury and have final arguments on Monday,

08:54:41

08:54:58

08:55:18

I guess that's November 15th. I'm going to fit it all into one day. We'll figure out everyone's time. With three defendants, it shouldn't be hard.

Now, if -- so that's my -- that's my thought if everyone uses all their hours. I mean, what does everyone think about that? I mean, if -- you know, there's strong consensus is that we just -- you know, you have Thursday off to prepare your arguments and then we do it on Friday, I'm fine with that, but I just -- with a trial of this magnitude, to have a 2-day break right after the arguments and instructions, I don't think's ideal, but, it's your case so you can think about that.

MR. WEINBERGER: Your Honor --

THE COURT: Now, if we -- if people don't use all their hours and we finish on Monday or Tuesday, at that point in time -- I don't think it's a good idea to have people have -- jury have 5 days off, and so I would then, you know, do closing arguments and instructions Thursday -- Wednesday, Thursday's off and then they start deliberating Friday. That's my -- that's my thought.

But again, you know, if there's an agreement on -- for everyone by something else, I don't have a problem with it. So you can think about it. You don't have to decide right now, but I think it makes sense to -- for everyone's planning to start thinking about that.

MR. WEINBERGER: Well, Your Honor, I would like to address one aspect of what you've talked about at the risk of. . . some displeasure perhaps on your part.

In terms of where we are in terms of the time that we've used, I think we have about 17 hours left and. . . could we have used our hours more efficiently? Perhaps some might suggest that to be the case.

We have tried carefully within the confines of what we have to do to prune down our case substantially, including the number of expert witnesses, and as the Court pointed out yesterday, it actually impacted somewhat on our presentation of the distribution side of the case.

I have no idea what defendants' intent is in terms of the presentation of their defense. If -- if they present the witnesses that appear to be what their plan is, actually it was my intent on Monday to request that we be given some additional time, with additional time granted to the defense also, for use in addressing the defendants' part of the case, realizing also that it's always been this Court's goal to ensure that this case ends before Thanksgiving. And I'm not --

THE COURT: And with enough time to deliberate before Thanksgiving.

MR. WEINBERGER: Right. Right. And, so, I'm not making a specific request at this point in time, but I

didn't want to, in light of what you've presented this morning, I didn't want to not tell you what our concerns are. And I'm happy to put it in writing and explain the basis for it and get it to you Monday morning, but I just wanted the Court to understand that that's what we're considering.

08:59:21

MR. STOFFELMAYR: Judge, may I saw a few words about that? Kaspar Stoffelmayr for Walgreens.

This would be -- the unfairness of this proposal is impossible to state. We objected to the Court's time limits. Plaintiffs endorsed them. You imposed them over our objection. We have planned every day and every element of our case around the time limits that we understood to be the rules that all parties would have to play by.

08:59:37

08:59:58

If we are going to say, no, never mind, that wasn't serious, we would -- every day of this trial would have been different. I can't even get my head around the idea that that was just -- the 75 hours was just a suggestion and if --

09:00:14

THE COURT: It was no suggestion.

MR. DELINSKY: And, Your Honor, if I could add, there has been no person who has said less in this trial than me, including starting with the very first witness who was our own asking maybe three or four questions to time again standing up and saying no questions for CVS

09:00:32

because we were budgeting for our case for the future. That bell can't be unrung.

And, Your Honor, if they are granted more time because they did not exert the discipline that we excerpted, that's a mistrial, and we will be seeking a mistrial. We can't change it. Their case is over. We cannot go back in time and now recapture the additional hours that we would have taken to make their case less compelling to the jury as it was coming in. That's a -- that's lost. And we can't change the rules now. We absolutely can't. And I would reiterate what Mr. Stoffelmayr said, Your Honor, nobody has been more vocal as well than my law firm and CVS in objecting to the 75 hours to the point, Your Honor, where Your Honor's last order on that called us -- said that our argument bordered on frivolity when we continued to challenge the time limits and were seeking around that.

And to at this point, after we've objected to, but -- and then accommodated, to say plaintiffs get extra accommodation in a way that -- we can't rescue this trial from that now. We were too far along. If this were raised the first day, at our Pretrial Conference, that would have been a different matter, but their case is over and the prejudice here would be just immeasurable, and it would be a mistrial, Your Honor.

MR. MAJORAS: Your Honor, John Majoras for

Walmart.

We join in all these well-stated objections.

THE COURT: All right. Well, I think defendants have raised some very good points, that it's really -- it would be -- I think it would be unfair to change the rules at this point in time. I mean, if you're talking about an hour or two or each side, I mean the difference between 75 and 76 or 77 for each side is not dramatic, but if you're talking about any significant change -- and I assume you are or else you wouldn't raise it -- I'd have to think long and hard about doing it, and the defendants have made some serious points.

So I -- you know, I -- I felt the time limits were fair when I made them. I mean, I've been a trial lawyer and I think -- candidly, I think both sides have benefitted by this because, you know, people have been efficient, and this trial's moving along and the jury -- I mean, we have an excellent jury, but I think part of the reason they're so attentive is because the case has moved along, and we haven't had a lot of repetitive questions. The defendants have been, you know -- they have only needed one person to ask a question, so. . . so I'm -- the plaintiffs can make their request, but I -- defendants have made some very good arguments, and I would have to think long and hard about whether it's fair to change things in any appreciable way at

this point.

So I think people should operate on the assumption that that 75 hours, and if everyone uses all 75 of their hours, that's when we're going to end. I mean, everyone can do the addition the same way I have.

I guess, you know, does anyone have a reaction? I mean, you can that about that. If everyone thinks, you know, we should just -- if we end Wednesday, Thursday is off and we do final arguments Friday, that's fine. I'm just thinking as a trial lawyer and, you know, as a judge, that's -- ideally you want the jury to at least begin their deliberations after you do the instructions and the closing arguments and not have a 48-hour break, but, there have been cases where it's happened that way. So you can think about it.

Okay.

MR. MAJORAS: Your Honor, speaking only for Walmart. If that timing works out the way you're now imagining it terms of the time, if we do end on Wednesday, my initial reaction is, only on behalf Walmart, is that makes sense in terms of what you described. I think as we go through next week we can have a better sense of the likely end date and we can adjust, but if you're looking for immediate reactions that's my immediate reaction.

MR. DELINSKY: And, Your Honor, CVS concurs in

that.

MR. STOFFELMAYR: I think we're in the same place, although we haven't had a chance to discuss it among ourselves.

09:05:14 THE COURT: All right. Well, you know, you can think about it and talk to the plaintiffs, and, again I -- I mean, this is obviously when it's in my discretion what to do, but I -- it makes sense. It's your case that you're trying, it's not my case.

09:05:28 Okay. And we can talk about that more next week and get a sense, and, again, candidly, that -- in my view, that's another reason that the trial may be just more efficient at this point without distribution claims.

I don't -- the -- it would just take some minor 09:05:52 adjustment in the instructions, just basically deleting the reference to distribution, but there are a lot of reasons why that makes sense, but again, I'll see what the -- plaintiffs have to decide what they want to do.

Okay.

09:06:09 MR. MAJORAS: Get the witness, Your Honor?

THE COURT: Yes. We can bring in the jury and have Dr. Wailes come back.

(Brief pause in proceedings.)

(Jury returned to courtroom at 9:08 a.m.)

09:09:01 THE COURT: Good morning, ladies and

gentlemen. Please be seated. I see you all have on your Browns lucky shirts and sweatshirts, so hope that they work.

All right, Doctor, I just want to remind you you're still under oath from yesterday.

09:09:13 And, Mr. Majoras, you may continue.

MR. MAJORAS: Thank you, Your Honor.

Good morning, folks.

Good morning, Dr. Wailes.

THE WITNESS: Good morning.

09:09:20 DIRECT EXAMINATION OF ROBERT E. WAILES, M.D.(CONT'D)

BY MR. MAJORAS:

Q Let's just reorient ourselves just a bit to where we were yesterday when we broke for the day yesterday, and you were testifying about your concerns about Mr. Catizone's red

09:09:31 flags; is that right?

A Yes.

Q And if you could just explain to us again, why is this important or of significance to you as a prescribing doctor specializing in pain management?

09:09:45 **A** Well, there's at least a couple reasons why it's important.

Number one, Catizone specific red flags as compared to general red flags capture so many patients of mine that would apply to my patient population and apply to many

09:10:02 different groups, like oncologists and end-of-life care, and

so it's an overbroad set of red flags that is not specific for terrible problems. They're very overbroad. So the fact that it catches 19.4 percent or approximately 1 out of 5 of all prescriptions means that it's not really very specific at all.

09:10:27

Secondly, the fact that he clearly states that all red flags must be resolved is problematic. I believe it should not be a mechanical stop like that, it should not be an absolute, it should -- you should allow pharmacists' judgment in whether to fill a prescription or not. It shouldn't be a bright line in the sand.

09:10:47

He makes very clear, and for at least two of his red flags, that the prescription should never be given for the combination of opioids and benzodiazapines, and then for the combination of three drugs, that would be opioids, benzodiazapines, and a muscle relaxant. And I've already given examples where those are used in my practice, not frequently, but occasionally. So you can't apply absolutes to those.

09:11:11

Furthermore, by him saying that they must be resolved implies that if there is a question -- and it's legitimate for pharmacists to have questions -- if they cannot be resolved, you, of course, would want to call the doctor or get in touch, and there are examples where that doesn't always work. There's examples where the doctor may not be

09:11:32

09:11:50

available at the time of the call. If he has to call an orthopedic surgeon and they're in surgery replacing a hip, they're not going to be out of surgery until 6:00 in the evening. Some pharmacies close at 5:00. They may call the doctor and they may not get the doctor until the on-call doctor gets back. There's plenty of examples where they may not be able to clearly resolve any of these -- some of the even simple red flags. And if they can't resolve them, it's my opinion that the pharmacist must have the patient's best interest in mind and not cause patient harm.

The consequence of delaying or denying prescriptions is significant. It has the potential to have patients go through withdrawal, and this can be very, very difficult.

So those are the main reasons why I'm opposed to Catizone's red flags as he presents them.

Q So let's go back to where we were yesterday where you were talking about some of the specific red flags, and I'd ask if Slide 34 could be put on the screen for you.

Could you explain what you mean in the information you're providing here?

A Yes. This is reflective of one of his red flags, and it's a red flag for when there's two different -- two or more different prescribers or doctors that are providing a controlled substance, and opioid in this case, and there's an overlap. And what that means by an overlap, it means

that if I write a 30-day prescription and someone refills it on a day or two or three, let's say three days early, that would be an overlap. If a different provider refilled that within the three days before -- so, for example, if I wrote
09:13:56 a regular routine prescription for a 30-day supply, and then the patient's scheduled to come back, we always have them come back before they run out of medicine, so you never come back on the day you run out, that would not be wise --

Q Dr. Wailes, I apologize for interrupting, but you put
09:14:14 some slides together specifically on this top. Would you like --

A Yes. Yes, I did.

Q If we can go to the next slide, please.

A This shows a graphic of what I was going through. If
09:14:24 a doctor gets -- or the patient gets a prescription on day 1 and the prescription's for 30 days from the physician, they come back and follow-up -- we can go to the next slide, please -- and the patient follows up with my PA or nurse practitioner. Very common scenario. That would flag --
09:14:47 that would cause this red flag to occur, and again, this is a very common scenario. There's an overlap and they get a prescription from someone -- a different prescriber. In our office we frequently share patients. If I'm in the surgery center doing procedures, my physician assistants frequently
09:15:05 help me write prescriptions for follow-up cases. So this --

and the next slide please -- would show a list of things that happen.

I need to let you know, this is a very common occurrence, to have two different doctors prescribe within, for example, the same month or the same period. Every patient that's referred to me, every patient that's referred to me, they're going to get a prescription from two different -- for opioids from two different doctors. I'm going to write them a new prescription. So by definition, they're going to have another prescription from a different doctor. That's two doctors that are going to be overlapping.

Again, we never want patients to come back on the last day of their prescription because the pharmacy may close, they may get sick and not be able to go pick it up. There's -- the pharmacy may not have that medication in stock. It's just not a wise thing to put yourself out like that.

Other examples are any of the emergency room visits. Emergency doctors and urgent cares are trained now to give very small doses of medicine. So if you go to an urgent care now, you're not going to get many days supply. You're going to get a few days' supply, 3 to 7 days probably, and you're going to want to follow up with your general practice doctor, internist, whatever your primary doctor is, or an

orthopedic surgeon, whatever the follow-up is, you're going to want to follow up before that few days' supply runs out if you're still having problems.

If you're injured when you're out of town you'll definitely get a prescription from a different doctor and come back and see your own doctor.

And also if you go to an academic institution -- this is very common. If you go to the Cleveland Clinic or University Hospital or University of Pittsburgh from Lake or Trumbull Counties, it's very common you're not going to have the same doctor write you the prescription each time. You're going to go to the Clinic, you may see the attending physician, the next time you may see the fellow or the resident or the intern. There's frequently at academic centers different people writing for the prescription.

Q Let's move to the next topic on -- in terms of your comments about the red flags, and this relates to short-acting opioids being received on the same day. If we can go to the next slide.

So I need to -- before you get into your concern about this, let's do a little definition building if we could.

First, what is a short-acting opioid?

A A short-acting opioid is one that has a relatively short duration. It's usually 4 to 6 hours. More frequently 4 hours of active life. And that would be the most common

things that you may be exposed to. I think we have a slide on the next -- our next slide shows some of the common drugs for this.

These are call generic names. You may be more familiar with just the terms Vicodin or Percocet, Tylenol with codeine or Tylenol Number 3. Those are all examples of short-acting opioids that don't have a long duration as compared to extended-release types of medications.

Q So in terms of treatment, if you have a short acting, and then I'm going to assume there's a long-acting opioid or there are long-acting opioids, is that right?

A Correct. There's many long-acting opioids, yes.

Q So describe -- well, first of all, let's go back to the previous slide if you would, please.

What is your concern about this particular red flag that Mr. Catizone identifies, receiving two short-acting opioids on the same day?

A Well, like other of Catizone's red flags, there's just a number of examples of things where it doesn't apply, or maybe I should say it applies and it really shouldn't. It shouldn't be a red flag if it's in the normal course of a -- the practice of medicine. And one clear example is if you have cancer patients, you frequently need to supply them different formulations of opioids to get through the day.

So, for example, if you have severe pain from any type

of cancer, you're going to get probably a short acting, you may be getting a long acting also, we'll go through that in the near future, so you may be getting too different types of medications there, but on the short-acting medicine that's what you're using for flare-ups in pain, for intermittent pain that comes up. If you're taking chemotherapy, you may have terrible nausea and vomiting and side effects from that chemotherapy. So it's very common for the oncologist, and sometimes in my case, to supply a prescription for those patients to not just have pills to take, but also use rectal suppositories. That's actually a really good way to provide medicines for people who have bad nausea and vomiting.

Other examples where you may do two short-actings to have alternatives is just realizing -- this is a little wonky, it's a little technical, but many of the short-acting medicines that you saw on that list come in two different formulations. One of the formulations is mixed with Tylenol, so the Percocet, Vicodin, Norco, Percodan, they're mixed with some other medicine, either Tylenol or aspirin, and that's the most common -- commonly used formulations. But if it has Tylenol in it, you don't want to give too much Tylenol. Actually, there's risks -- significant risks with using too much Tylenol on a regular basis.

So if someone's on a fairly significant dose of

short-acting medicine with the Tylenol, a lot of time the use of that medicine is limited by how much Tylenol you can give in a day. So if I want to bump this patient on a dose of short-acting medicines to a little bit higher dose, I may use a formulation that has no Tylenol in it at all. So I may have them on 10 milligrams of Norco or a Vicodin or a Percocet, and those are all mixed with Tylenol, but if they're taking maybe more than four or six of those a day and I want to bump them up with a little bit more of the opioid, I would give them a plain opioid without the Tylenol. And that would be the same drug in two different formulations. And that's another example where you may use two different short-actings at the same time.

Q So if in fact one is looking to determine whether a patient has been prescribed two short-acting opioids is it important to understand whether those medications are in fact short or long-acting opioids?

A That's correct.

Q So let's go to the next slide. There was a -- during the testimony of Mr. Catizone -- I'm sorry, one more slide -- during the testimony of Mr. Catizone there were questions that we raised with him as to whether methadone is a short-acting or long-acting opioid. So I'll put the same question to you.

A Methadone is a long-acting opioid. There's no

question about this. It is -- FDA defines it as that. Every medical textbook and pharmacy reference and journal article would describe opioid -- I mean, methadone as a long acting. It's half-life is approximately 24 hours. It's a long-acting medication.

Q Now, there are multiple formulations of methadone; is that right?

A Correct, there --

Q What --

A Even immediate release. It still is a long-acting opioid no matter what formulations it's coming in.

Q So if a red flag were to identify methadone as one of the short-acting prescriptions that has been given, what is your opinion of that?

A That's clearly a mistake.

Q Okay. Let's move to the next slide, please.

This is another one of your comments -- examples that you're giving with your concerns with Mr. Catizone's red flags; is that right?

A Yes, it is.

Q Could you explain it, please?

A So, I'm not sure how he came up with this, but in essence what this is is a 200-day supply, just think about 210 days as 7 months, right, it's 30 times 7, and he's saying within 6 months, which is, let's say, 180 days, so 6

times 30, and this would trip up multiple times just with normal prescribing. And I'll just explain the scenario where this applies most easily, and then I'll go on to explain other ways that it gets tripped up.

09:23:41 So if I give a regular prescription every month, and some months have 31 days, by the way, but a month prescription, every day on day 1 of when the prescription's due, after 6 months the patient would be due for their 7th month prescription, right? So on a day 180, let's say, 09:24:05 they're due for their next prescription for the seventh month. Now, this -- that seventh month prescription, especially if it's 31 days or you've had 31 days in any of the months preceding, you're already going to have more than -- for the seventh month it's already going to be more 09:24:26 than a 210-day day supply.

Okay. So already by definition if you have 31-day months and you do a 7-month supply, it's going to be more than 210 days, and, again, you would always fill the seventh month before the end of the sixth month, even if it's one 09:24:48 day before. You don't want to fill the prescription after you run out or on the very last day. So just filling the last month prescription a day before the end of the sixth month is going to trigger this.

Now -- so that's one clear easy example. Another 09:25:06 example --

Q I'm sorry, Dr. Wailes. I interrupt you from time to time, I apologize.

Before you move on, though, I want to ask you, in terms of the example that you just spoke about, can you give the jury some sense as to whether that's just some far-out example I came up with or whether it actually fits within your practice and experience?

A In my practice and experience this happens maybe the majority of the time on routine prescribing. Again, it's every month you're going to give the seventh month, which gets you over the 210-day supply. You're going to give that before the end of the sixth month. So it's common.

Q Okay. Now, I'll try to bring you back to where I interrupted you. You were going to talk about another example which I think you have a slide on.

A Right. So, also, within this red flag, he counts all opioids prescribed. And so if you count all opioids prescribed and they happen to be getting two different opioids -- and I'm going to run this through example to explain why it's common to have two different opioids -- then you're going to trip up the 7-month supply in less than 6 months very quickly because he's counting for both of those opioids. And let me go through the example and then I'll come back and try to tie that up.

So what I want to show you, I want to tell you the

punch line first, but this is going to demonstrate where it's very common to use a long acting and a short acting together, and this is very true for many of my patients with chronic pain or cancer pain and end-of-life pain, which is
09:26:43 fairly constant throughout the day with variation. And this graphic is meant to show -- the red is the pain that the patient's experiencing. And there's some baseline pain all the time in the patients that I just described, and within the baseline, they always have some pain, but if they do
09:27:01 activities, such as going to physical therapy or trying to garden in this example, or whatever activity, it may be trying to prepare a meal, it may be trying to go for a short walk, they're going to have increased pain during that time.

So -- next slide, please -- one way to treat that is
09:27:20 to provide them a long-acting opioid, and again, this is for that patient population. This is not for simple acute pain or something like that, but if they have baseline pain, the long-acting opioid is kind of shown in green here, overlaps that baseline pain, and that can be very useful, and
09:27:39 long-acting opioids are very useful in helping chronic pain and cancer pain and end-of-life pain.

But how do we cover those other areas of pain? What we do -- next slide, please -- is we add intermittent or occasional -- thank you -- short acting, and that's what the
09:27:59 little green humps are designed to show, those are short

acting, of short duration, but they try to cover -- and it's not perfect, never is perfect -- but it tries to cover those times when you may be more active. And we counsel our patients to -- if you know you're going to physical therapy or you know you're going to go for a short walk or you're going to have increased pain, try to anticipate it and take it ahead of time.

09:28:14

Again, our goal with medication therapy is to increase the patient's activity. The more they can exercise and be active, the better outcome they're going to be, so that's an important way to look at this.

09:28:30

So, many of our patients -- to tie it up and -- is that many of our patients are on two opioids at a time, and his particular red flag would count the long-term opioid every month and then he would count the short-term monthly supply also every month and, so, on paper, you would go through 7 months of medications in 3 and a half months because, again, there's two different opioids. And that's just, again, examples of common clinical scenarios that would be a positive red flag under Catizone's red flag criteria.

09:28:46

09:29:08

Q If we could then turn to our next slide and one of your -- and your comments about Mr. Catizone's red flags, this relates to -- and we heard testimony about this -- whether a patient pays cash or doesn't use insurance for

09:29:28

filling a prescription.

What is your concern about that red flag?

A I'm very concerned about that because many of my patients are uninsured. In the United States, over 10 percent of the population doesn't have insurance, doesn't have Medicare, doesn't have Medicaid, doesn't have any insurance. Those patients have to pay cash.

In addition, the Medicare program historically has had what's called a donut hole, and I can go into as much detail as wanted, as desired.

Q Why don't you do that briefly.

A I'll try. It's a complicated and not a very logical scenario and the good news there is it's been phased out literally this year, but up till this year Medicare Part D -- again, there's different parts of Medicare, but for the Medicare prescription coverage is called Part D, and if Medicare patients pay -- and it's usually extra for Part D -- if they pay for that, they get prescription coverage. Sounds good. And they only have co-pays up until a certain amount of cost is expended, and in each year that certain amount changed until 2001 when it went away -- 2021. I'm sorry, just this year.

So you got to get a co-pay up until a certain time. And then, at that time, you had to pay cash for your medications. So it was a limited insurance, and you had to

pay cash for your medications after you reached a certain threshold. And so many patients with Medicare would exceed that threshold and have to pay cash for their medicines.

Now, Medicare not only covers the elderly, it also
09:31:22 covers the disabled. If you're disabled for 2 or more years, you're eligible for Medicare coverage, and many of my patients that are chronic pain patients are medically disabled and have Medicare as well. And this applies to them. And so the donut hole is that period of time where
09:31:42 you have to pay cash for all your drugs.

The reason why it's called a donut hole is after you go to a next threshold, it's maybe $2,000 more or something, and it varied every year, until you reach that next threshold, you paid cash, but once you reach the next
09:32:02 threshold then they had what's called catastrophic coverage and they would kick in coverage again where you would have a co-pay and the insurance would cover the rest.

So, anyway, that's a weird situation, but it applies to Medicare patients, and Medicare patients that get
09:32:20 medicines on a regular basis know all about the donut hole and having to pay cash for that.

Q And is that information you provided -- which, thank you, was very clear to me -- is that something that you have to discuss with your patients from time to time?

09:32:33 **A** Occasionally it comes up because if they're paying

cash, they're always asking me how much does the drug cost, and I think that's -- those are relevant questions, yeah.

Q Let's move to your next slide, which is 46 by my count. And this is -- this is another comment you had with respect to Mr. Catizone's flags 5 through 8, so there were four different red flags that he talked about here.

09:32:52

We've had -- we've had a fair amount of discussion, in fact you and I have had some discussion about the use of opioids, benzodiazapines, and muscle relaxers.

09:33:12

Are you familiar with the phrase "trinity"?

A I am familiar with that, yes.

Q And when you talk about trinity, at least with respect to these products, that's the combination we're talking about, these three products on the screen?

09:33:22

A Right. The trinity describes all three at the same time, yes.

Q So what is your concern about Mr. Catizone's red flags in this regard?

A Well, again, I'm concerned about his mechanistic

09:33:34

rigidity regarding this. I've already given examples -- we talked about spinal cord injuries, stroke, and other -- multiple sclerosis, severe types of problems that occasionally, not frequently, but occasionally need to have all three of these drugs together. I've also talked about

09:33:52

end-of-life issues and hospice and cancer patients where

opioids where benzodiazapines are used in combination. And what I'm concerned about is that there are clinical situations, and they're not many as I say, but there are definitely clinical situations where you need to give all three medications. And I'm concerned when I read Mr. Catizone's report that he clearly and overtly states that that's not appropriate and not right.

09:34:12

On Page 38 of this supplemental report he says that the -- this trinity of three different medications is not medically legitimate prescription. And if I've written that, and I've have, he's calling my prescriptions not medically legitimate.

09:34:35

Now, frankly, that sounds to me like a medical opinion. I practice within the standard of care, and I think they're medically legitimate prescriptions. He says that they should never be utilized, likewise, on just the combination of an opioid and a benzodiazapine, which I've told you is used very commonly, and in my practice it's used not uncommonly. We know there's risks, we know -- we can talk about the risks, we can talk about the fact that it's more common in overdoses, but in the appropriate dosing and medical supervision and monitoring, it can be a very useful combination for specific conditions.

09:34:55

09:35:16

MR. WEINBERGER: Your Honor, objection.

Can we have a sidebar?

09:35:30

(Proceedings at sidebar.)

Your Honor, the reason for the objection is that he is -- with respect to the opinion that Catizone testified that the two -- combination of two out of the three is not a legitimate prescription is absolutely incorrect and a misstatement of the record. It is clearly a red flag, but he never testified that just two out of the three was medically illegitimate. You know, it's one thing to have one expert testify about his criticisms of another expert. You know, he has done that multiple times in this and I question the appropriateness of that, but be that as it may, a -- this misquoting of a -- what's contained in a report is absolutely improper.

THE COURT: Well, I don't know that it's intentional, I don't know if it's a mistake, but you can certainly cross-examine him on it and shake him.

MR. MAJORAS: Your Honor -- I'm sorry, Your Honor.

In -- obviously he doesn't know the testimony. We've been restricted from showing him the actual testimony. He made a specific reference to the supplemental report of Mr. Catizone, and if they want to bring that report out and show him it's wrong, then obviously they can do that in cross-examination.

With respect to --

THE COURT: Has this within seen the supplement report of Catizone?

MR. MAJORAS: Yes, he has seen the reports of Mr. Catizone.

09:37:26 THE COURT: All right. Maybe he's made a mistake.

And so, Mr. Weinberger, you can point out that he's, you know, has been wrong, not precise, not careful, whatever you're going to say and shake him that way. That's fine.

09:37:41 But, I mean, he said what he said. If he's wrong, he's wrong, and you can point that out.

MR. MAJORAS: And it's -- it's also consistent with what Mr. Catizone actually did testify, which is that the red flag, the trinity red flag, cannot be cleared. His

09:37:57 testimony as to how --

MR. WEINBERGER: Your Honor, okay.

MR. MAJORAS: -- as to how two different medications are used is simply his testimony as to how we use them.

09:38:05 MR. WEINBERGER: Your Honor, that's totally incorrect, but that's okay, we'll cross on this.

THE COURT: You can cross him and you can show him Catizone's report, which is what he's testifying about. And if he's wrong about Catizone's report, you can point

09:38:16 that out to the jury. That's fine.

MR. STOFFELMAYR: Judge, before we wrap up, Mr. Lanier pointed this out to me the other day. It appears the jurors can hear Mr. Weinberger. Obviously, I'm sure -- I know it's unintentional, but we all just need to be careful about that.

09:38:30

THE COURT: Mr. Pitts, maybe we'll get white noise louder. All right? Please, let's make the white noise louder.

MR. LANIER: Your Honor, my argument was not that Mr. Weinberger could be heard, his voice projects away from the panel. My comment was that Mr. Stoffelmayr could be heard.

09:38:45

THE COURT: All right. Well, I've asked Mr. -- everyone should keep their voices down.

MR. MAJORAS: I'm at the kid's table, Your Honor.

09:38:58

THE COURT: But we're going to get the white noise louder.

All right. Thank you.

(In open court at 9:39 a.m.)

09:39:21

BY MR. MAJORAS:

Q Dr. Wailes, frankly, it's unclear to me as to whether you may have been interrupted in what you were saying. Had you completed your answer?

A Not exactly.

09:39:28

Q Please do.

A I think I was in the part about just the combination of an opioid and a benzodiazapine. We've already talked about the trinity, but just the two of them, again, do apply in my practice, and in his supplemental report he uses the phrase that this combination is contraindicated is the word he used. In medical parlance, that means should never be used. And again, I think that's a medical decision as to when it's appropriate to use these particular two medications together, and I take that very seriously and everyone does when prescribing. They look at the pros and cons and risk and benefits, and that seems to be a medical decision. So I'm not comfortable with saying that all patients who use those two medicines together is contraindicated.

And I'm also really concerned about patient safety. If he was or other pharmacists were to deny prescriptions for those patients, again, they could go through withdrawal and have terrible problems. And so it all boils down to patient safety.

Q Dr. Wailes, I just want to make sure a couple things are clear here. You've not had the opportunity to either watch Mr. Catizone's testimony or read it, have you?

A No. I was talking about his report. I --

Q That's where I want to go just so we're clear. When

you talk about the report, these are the reports that expert witnesses such as yourself and Mr. Catizone submit during the course of the case; right?

A Correct. Yes.

09:41:03 **Q** And he had -- he had multiple reports, one of which is called the supplemental report?

A Yes. Correct.

Q And that's what you're referring to; is that right?

A Yes, it is.

09:41:10 **Q** Okay. Let's go to our next slide, which by my count should be 48. I think we talked about 47.

This now goes to Mr. Catizone's flags Number 12 and 13 which relate to the same strength medication and multiple patients receiving a similar prescription if not identical

09:41:35 prescription in a one-hour period.

What's your concern?

A Right. This is, again, kind of a strange red flag because it applies to certain types of situations that do occur on not infrequent basis. And again, if you're a

09:41:52 practicing pharmacist you would see this occasionally.

And if you can go to the next slide, there's many different examples where doctors are -- have a routine. I mean, the easiest example would be an orthopedic surgeon. You can do the next part of that slide if you want. But

09:42:09 arthroscopies, they'll line up 4, 5, 6, 10 arthroscopies in

the same day, and they have the same routine for postoperative pain for arthroscopies. They're going to give a certain number of Vicodin for a certain number of days. It's just a routine that they do.

09:42:23 **Q** Dr. Wailes, just so we're clear on some terminology -- I unfortunately have direct experience -- but could you explain what an arthroscopy is?

A It's where you put a scope into the knee to do repair work on the inside of the knee. So you may have a meniscus

09:42:38 tear or something like that. It's very common with arthritis and athletic injuries to have knee problems, and this is oftentimes the first approach to trying to repair a knee problem is what's called a knee arthroscopy. I apologize, I throw medical terms out easily.

09:42:56 And so many surgeons have routine procedures that they do. Another example would be an oral surgeon doing wisdom teeth. That's common. We all know about that. And I guarantee you they just have a routine that they use for postoperative pain relief. They'll give a certain number of

09:43:14 pills, the certain -- same pills, same number, and I'm not sure how Mr. Catizone came up with the hour thing. I guess that's when they arrive at the pharmacy, because prescriptions don't have a time written when we write them. They have the date, of course, but it doesn't say when we

09:43:31 write them. So the hour, I guess, is if all the patients

show up within one half or happen to be at the same pharmacy within an hour, that's where he would be concerned. And so there may be four patients from urgent care, they have routines for what they see for minor injuries and may use, again, the same drug and the same dose.

09:43:46

Burn doctors, rheumatologists, see routine arthritis problems. And rheumatologists are similar to my specialty because they deal with a lot of chronic pain. Rheumatologists are arthritis doctors, and there's many types of arthritis. So they deal with a lot of chronic pain because arthritis is an example where people have long-term duration pain.

09:44:05

And, of course, pain management doctors, some of us have routines also. I don't use the same medications for every patient, but in the course of a day, there may be four patients that actually get the same month supply of Vicodin, certain prescription, and they could show up at the same time. So it's just examples of -- examples of what we call pattern prescribing, is that some doctors just have routines and apply it to multiple patients.

09:44:19

09:44:38

Q Is pattern prescribing a potential issue?

A Not usually, no.

Q I'd like to change topics now if I could, Dr. Wailes.

Do doctors -- in your experience, do doctors interact from time to time with pharmaceutical manufacturers?

09:44:56

A That's possible, yes.

Q How about manufacturers of devices that you may use in your practice?

A Yes.

09:45:09 **Q** Have you done that?

A Could you rephrase the question?

Q Sure. And I'm -- I just used the word interact.

So, from time to time do physicians such as yourself interact with either representatives of manufacturers of

09:45:25 pharmaceutical products or devices that you may use in your practice?

A Yes.

Q And why do you do that?

A I guess probably the most common interaction that we

09:45:35 would have is they may bring us lunch and tell us what the latest, you know, changes are in their equipment or medications. They may try to give us updates or something like that, educate us as to what's new or different or information about their product, whatever it is.

09:45:52 **Q** And from your perspective, what is the value or not in those interactions?

A I think it's interesting. Most lunch conversations are 5 or 10 minutes as we kind of just, you know, throw a sandwich down or something like that. It doesn't happen

09:46:06 very often for me. Actually, we don't have that many reps

come by for lunch, but I sometimes find it useful information, but mostly it just reaffirms what I've already got through my continuing medical education and other sources of information.

09:46:23 **Q** So that was -- and I was going to ask you, how do you go about evaluating what you were hearing from someone who is actually making the product and talking to you about it?

A Well, it's based on your experience and training and other exposure to the same material. And, so, again, we're

09:46:39 required to do continuing medical education, and so we go to continuing medical education courses, we read journal articles routinely in our specialty to keep up to date with what's going on, and, so, really, at all points in time, I have a pretty good feel for the market of different choices

09:46:57 of medications and of different devices that I use, and I know there's pros and cons with each one. I know the risks and benefits that's up to me as a physician making decisions to be well informed.

Q And you have heard -- we had some discussion in this

09:47:14 case about Purdue Pharma, and I'm just going to ask you a simple question. You have heard that Purdue Pharma had been investigated and pled guilty to federal charges at some point in time?

A I have a general understanding of that, yes.

09:47:26 **Q** You earlier described some professional associations

that you've been involved with; right?

A Yes.

Q Looking back over time in your interaction and your work in those associations, do you have concerns about whether any of those organizations were collaborating with drug manufacturers to mislead doctors?

A There's a long history of support from device companies -- in my specialty -- I'm going to talk about my specialty -- there's a long history of support for organizations from many of the device companies and pharmaceutical companies and so forth for our educational meetings, other -- mostly just educational meetings, I think, is probably the most common thing that they would donate money to. And we have very strict disclaimers, lecturers have to disclose if they're a paid lecturer for a company. They have to disclose that. And so we usually know up front if they're, if you will, on the payroll of a thing.

Most slides have to be vetted by the company and they get vetted by our association to make sure there's not bias. In fact, to qualify for CME now, we have to be surveyed after taking a course and one of the main -- I think it's a standard question because I see it pretty much every time, I think, is was there commercial bias in the presentation.

So back to your question, though, is that I think it's

common for organizations that put on educational meetings to look for support, and I think they get that support from a number of different places, including pharmaceutical companies and device companies.

09:49:17 **Q** And you had mentioned that you were aware of the legal issues that Purdue Pharma had been facing at various times.

How does that impact or factor into your analysis of products they may manufacture?

A Well, it's my general understanding, and I'm not

09:49:34 expert in what happened with that litigation or the settlement involved, I'm not expert in that, but it's my understanding that they admitted to excessive marketing and some marketing that was not accurate, wasn't all scientifically based. That's my understanding of what they

09:49:55 got in trouble for.

Q And to be clear, my question wasn't what so much your understanding was, the question is does it have any impact on you as a prescribing physician that has used opioid products to treat your patients over the 37 years you've

09:50:09 been doing it?

A Yeah. None of that money went directly to me, you know, so I wasn't paid to do stuff. I'm not a key opinion leader. I didn't do lectures for Pharma. I was -- I did go to meetings where they were one of the supporters of the

09:50:26 educational foundation -- or the education and so forth, but

even on the board of directors now at the American Academy of Pain Medicine, there's no direct payments or any money goes directly to any board member or leader within the organization unless you're a consultant for the company, and there are some, but most are not.

09:50:47

So for me personally, I never felt a significant influence that way. I was aware of their marketing, and they did market very aggressively, I think, in the -- especially in the mid 2000s when OxyContin came out, and so I was aware of that, but still, every decision that I make as a physician is based on the individual patient's needs and what I think is going to be best for them.

09:51:05

Q And in terms, again, of the experience you have, the 37 years of working with -- I won't even ask you to identify how many patients you've treated over that time -- what have you been able to observe in terms of the effectiveness of opioid treatment in your patients?

09:51:21

A Well, clearly, ever since the start of my career in 1984, we've known that opioids help pain. And so it's been clear that it's been very useful for all types of pain. It needs to be applied carefully. Opioids, like every other medicines, have side effects. But in my population, over the course of my career, they've been an important part of my treatment plan for chronic pain patients -- chronic and other pain patients.

09:51:41

09:52:00

Q So, Dr. Wailes, as we sort of wrap my portion of the questioning of this up, I want to try to see if we can pull all this together, the conversations we had today and yesterday. And you've put together some slides outlining your specific opinions in this case. So let's see if we can go through those quickly. I'm not going to ask you a lot of detail, but if there's something you see you want to explain, please do.

So if we can go to Slide 50, please.

And is this one of the opinions that you want the jury to take from your testimony?

A Yes, and clearly restating what we've just said is that the use of opioids has been standard of care for treating acute and chronic pain for many years, even though we know the risks are there for significant side effects, including addiction and overdose. We've -- those have been well known throughout my entire career. Since medical school I've known about those serious risks. Yet, luckily, the benefits outweigh the risks the vast majority of the time.

Q If we can go to your next opinion.

You talk about the risk mitigating measures used in clinical practice have evolved over time which has helped to address the risk of abuse and diversion, but the clinical benefits of opioids have not fluctuated.

Is that your opinion, sir?

A Yes, it is.

Q Just so we're clear, when you talk about risk mitigation or risk mitigating matters, could you tell us briefly what that is?

A So those are the measures that we use to try to prevent or sometimes decrease the harm in patients that may be at risk of addiction or overuse. And so those are things that we do now, and many of these we didn't do very frequently in the past so this is part of the evolution that we have learned over time.

And some of those things are like urinary drug testing. Really important to see if they have illicit drugs or what else is going on in their life with testing.

The use of OARRS in Ohio, or the prescription monitoring drug program, where you can see who else is prescribing for the patient and make sure that you know exactly what they're taking in terms of prescription drugs.

The frequent office visits where you actually monitor the patient, you see them, you make sure that they're not running out of medicines early. We do a lot of controls that we can assess how a patient's doing and try to minimize the risk.

We also have much better informed consent now. We manage expectations better now in terms of what to expect

with their opioid prescription. We recommend lock boxes. There's a lot of -- for their medications so their kids or the house cleaner doesn't steal their medicines and avoid diversion.

09:55:00 We do a lot of things to try to decrease the risk of misuse and addiction.

Q And you mention in this slide about the clinical practice and using risk mitigation factors or measures has evolved over time. This evolution over time, does that

09:55:18 relate to the standard of care that you've testified about?

A Yes, just like the standard of care has evolved over time, some of that involves using these different items to decrease the risk. Those have come into being more recently. For example, just the urinary drug testing was

09:55:35 really since 2010 has it really gained wide acceptance and how found out useful that is.

Q Okay.

A So it's been over time, yes.

Q I'm sorry. And I think that leads into your next

09:55:45 opinion that you've summarized. If you could -- if you could read that to us, please.

A Yeah. I'm going to go in reverse order and read the bottom first.

There was recognition in the 1990s that pain was being

09:55:57 undertreated and patients were suffering. And the standard

of care on how to treat pain, particularly chronic pain, has evolved over the past several decades.

Q And is that one of the opinions that you want to leave with the jury as you testify in this case?

09:56:13 **A** Yes.

Q If we could turn to the next slide, please.

Again, I'll ask you if you would read this.

A It says, pharmacists cannot diagnosis a patient or practice medicine.

09:56:25 It says, refusals or delays to dispense a legitimate prescription are dangerous and can be life threatening. And that relates, of course, to the potential to go through withdrawal, even with a delay, to go through withdrawal, and that really can affect patient safety.

09:56:44 **Q** And the final summary of your opinions that you have offered from your position as an expert in pain management and practicing specialist in that over the last 37 years, we talked this morning and yesterday afternoon about Mr. Catizone's red flags.

09:57:02 Could you please read this opinion?

A This kind of summarizes that my comments and opinion that Mr. Catizone's red flags capture a host of prescribing circumstances that fall well within the medical standard of care. That's kind of what I've been talking about this

09:57:18 morning and at the end of yesterday.

And if his -- Mr. Catizone's red flags were implemented in clinical practice, it would significantly interfere with legitimate patient care and safety.

MR. MAJORAS: Thank you, Dr. Wailes.

09:57:34 Your Honor, I pass the witness.

THE COURT: Okay.

MR. LANIER: Your Honor, is it plaintiffs' turn or do the other defendants --

THE COURT: Well, I'll inquire. I'm assuming

09:57:52 they don't, but I always should inquire, you're right.

Mr. Swanson?

MR. SWANSON: Nothing for Walgreens. Thank you, Your Honor.

THE COURT: Okay. Then you're up, Mr. Lanier.

09:58:16 MR. LANIER: Thank you, Judge.

May it please the Court.

Ladies and gentlemen, may it please you as well.

CROSS-EXAMINATION OF ROBERT E. WAILES, M.D.

BY MR. LANIER:

09:58:22 **Q** Sir, my name is Mark Lanier. You and I have had not the pleasure of meeting. Is that true?

A That's true.

Q Welcome from California.

A Thank you.

09:58:30 **Q** I've got a lot of questions to ask you. I think what

you've said is very serious thing and I really want to challenge you on some stuff. Okay?

I've got a road map for you, but before we get to the road map, I want to ask you some general questions that we'll use later on, just simple true/false questions.

That's you, isn't it? Did I get the right picture?

A That's me.

Q All right. Always want to do that right.

True or false. Recognizing possible red flags for invalid opioid prescriptions is a pharmacist's responsibility. True or false?

A Generic red flags, that would be true.

Q Not stepping in to investigate or resolve red flags can lead to legal action under the Controlled Substances Act. True or false?

A I'm not sure how to interpret that. I don't -- could you explain the question a little bit better, please?

Q Yes, sir. Take the two together, recognizing possible red flags for invalid opioid prescription is a pharmacist's responsibility, and not stepping in to investigate or resolve red flags can lead to legal action under the Controlled Substances Act. True or false?

MR. MAJORAS: Objection. Scope. Expertise.

THE COURT: Let's go on the headphones.

(Proceedings at sidebar.)

THE COURT: Well, I heard the objection, Mr. Majoras. Obviously this witness has testified that he himself was a registrant, so he's got to know at least what a doctor's obligations under the CSA is, and I assume he knows what a pharmacist's obligation, but --

10:00:39

MR. WEINBERGER: Well, not -- you don't have to just assume it. I mean, he -- his whole testimony is centered around the pharmacist's conduct. So to --

THE COURT: Well, that's what I -- I'll allow the question. I figure he should know this.

10:00:54

(In open court at 10:00 a.m.)

BY MR. LANIER:

Q Please answer the question, sir. True or false?

A It's my understanding -- and I apologize, I don't think red flags, that term, is used in the Controlled Substances Act, so I'm not sure how this specifically applies. I'm not an attorney, so I am familiar with some of the Controlled Substances Act, but I'm not familiar with any reference to red flags in that act.

10:01:14

Q So is your answer I don't know?

10:01:31

MR. MAJORAS: Objection. His answer is what his answer is.

THE COURT: Overruled.

You can answer that question, sir.

THE WITNESS: I'm not familiar with the

10:01:46

requirement to investigate specific red flags in the Controlled Substances Act. I'm not familiar with it.

BY MR. LANIER:

Q So you don't know. That's fair to say?

10:01:57 **A** I'm not clear on that question.

Q I'll put not clear.

Is that fair?

A Yes.

Q Okay. Next, I'd like to go through a list of red

10:02:12 flags and see if you would agree that these are red flags.

Opioid prescription concerns: Red flags.

True or false?

Agree, don't agree, whatever you want to do on the answer.

10:02:25 Multiple customers with prescriptions written by one prescriber for the same drugs in the same quantities. Red flag or not?

A How are you defining red flag?

Q A red flag is something that is a pharmacist's

10:02:45 responsibility to identify where the pharmacist needs to step in to investigate or resolve or it could lead to legal action under the Controlled Substances Act.

A So my answer to that is that it is possible to have concern over this, but it's certainly not one of -- not a

10:03:08 legitimate red line in the sand where you would not fill a

prescription if you know -- if you know the prescriber and you know what they do in the regular course of their practice. So you would need more information to know if this is a legitimate red flag or not.

10:03:24 **Q** You understand the concept of red flag is given by Dr. Catizone, as given my witnesses for the defendants. The idea of a red flag is stop, be on alert, resolve the red flag, and then either fill or refuse to fill.

You understand that's what a red flag is? It's stop, 10:03:49 be alert, and then resolve it, investigate it.

A My concept of a red flag --

MR. DELINSKY: Objection, Your Honor. Objection, Your Honor.

THE COURT: Let's go on the headphones.

10:04:05 (Proceedings at sidebar.)

THE COURT: What's the objection?

MR. DELINSKY: Your Honor, the objection was that testimony of what testimony -- Mr. Lanier's testimony in his question about what the question in trial has been 10:04:20 and what positions the defendants hold or not hold.

THE COURT: All right. I'll sustain that. You can ask -- I'll sustain that question, so ask another one, please.

(In open court at 10:04 a.m.)

10:04:43 BY MR. LANIER:

Q You understand that a red flag, as a concept of stop, don't just fill it, investigate it, resolve the red flag, and then either fill or refuse to fill. That's the concept of a red flag.

10:05:01 Now, with that definition, is this a red flag?

A That's not my understanding of red flag, so I think we have a slightly different concept of red flags. That's what I'm challenged with.

Q All right. Let's write down your definition. What do you think to a pharmacist a red flag means? So let's make sure we're clear. We're talking to a pharmacist, you've been testifying about that quite a bit, to a pharmacist, a red flag on an opioid prescription is what?

A It's a prompt for further consideration to see if the prescription is valid and appropriate -- valid and. . . how should I say. . . not fraudulent. . . and written by a licensed physician in the regular course of their practice.

Q Anything else?

A I think that's in general terms what a red flag concept is.

Q Did I write it right?

MR. MAJORAS: Objection. This isn't the record.

Is that a question?

MR. LANIER: I'm going to come back with this

to you. I want to make sure I've accurately represented it to you.

THE COURT: That's a fair question.

Overruled.

10:06:58 THE WITNESS: Yes, that's -- that's fair, I believe.

BY MR. LANIER:

Q So then within the framework of how you believe a pharmacist defines a red flag is multiple customers with

10:07:18 prescriptions written by one prescriber for the same drugs in the same quantities, is that a red flag?

A Not routinely, but possibly.

Q Customers with the same last name and street address presenting similar prescriptions on the same day or within a

10:07:46 short time span.

Red flag or not?

A Possible red flag.

Q Two short-acting opiates prescribed together.

Red flag or not?

10:08:02 **A** Possible red flag.

Q Patients traveling long distances to fill prescriptions. The prescriber's located far from the pharmacy.

Red flag or not?

10:08:16 **A** Possible.

Q Unusually large quantity of a controlled substance.

Red flag or not?

A Could you define that better, please?

Q No. That's the definition at it -- that's all I got.

10:08:34 **A** I'm not sure what that is. I don't know what large quantity is.

Q Well, you know what the CDC says in terms of size, don't you?

A I'm sorry. Repeat the question.

10:08:43 **Q** You know what the CDC policy is on what size should be for dosing and what's considered large; right?

A No, I don't.

Q Okay. So on this one you'll just say I can't answer. Fair?

10:08:54 **A** Correct.

Q A pattern prescribing. For example, a dentist writes the same prescription for oxycodone for all patients regardless of the procedure.

A That would not usually be a red flag.

10:09:22 **Q** Irregular dosing instructions.

Red flag?

A Don't know how to interpret that. I would need more information.

Q All right. I'll say can't answer.

10:09:30 MR. MAJORAS: Objection. That's not -- that's

not his testimony.

BY MR. LANIER:

Q Without more info. Is that not your thing?

A Yes.

10:09:42 **Q** Lack of individualized therapy or dosing.

Red flag or not?

A I would need more information. I don't really understand what that means.

Q Early fills or refills.

10:09:58 Red flag?

A Possible.

Q Other pharmacies' refusal to fill the prescriptions.

Red flag?

A Possible.

10:10:17 **Q** Do you know what ER and LA stand for in a formulation?

A Yes.

Q Why don't you tell us, early relief --

A Extended relief or long acting.

Q Extended relief long-acting formulation for a patient with no history of opioid prescription use based on interview and PDMP.

Red flag?

A Possible.

Q The PDM report shows overlapping dates on prescriptions.

Red flag?

A Only possible.

Q The PDM report shows multiple prescribers or pharmacies.

10:11:05 Red flag?

A Possible.

Q Patient uses cash rather than insurance. I think you've already told us you don't agree with that red flag; right?

10:11:18 **A** What I said is there's numerous examples where it doesn't apply and there's -- it's frequently legitimate reasons for explaining that.

Q Red flags can be resolved?

A Yes, they can.

10:11:30 **Q** My question is, should a pharmacist look into it?

A Possible, yes.

Q Prescription is inconsistent with the prescriber's practice area.

Red flag or not?

10:11:48 **A** Possible.

Q Indication on a prescription is different from the patient's description.

Red flag or not?

A I'm not sure what you mean by that.

10:12:07 **Q** Don't follow, or don't understand?

A Correct. I would need more information.

Q Dosage is above guideline recommendations.

Red flag?

A Possible.

10:12:24 **Q** A potentially dangerous combination is prescribed, opioid with a benzodiazapine and/or another central nervous system depressant and/or a stimulant.

Red flag?

A Possible.

10:12:41 **Q** The prescriber's DEA number does not match records.

Red flag?

A So doesn't match records? You're saying that a -- the prescriber doesn't have a -- has the wrong DEA number?

Q Um-hmm.

10:13:04 **A** That would probably be a red flag.

Q Prescription is not presented within a reasonable time for the indication, i.e., prescription for acute injury or surgery dated several days earlier.

Red flag?

10:13:16 **A** Possible.

Q Illegible questionable abbreviations, signatures different from that on file, different ink.

Red flag?

A Yes.

10:13:37 **Q** So if these red flags -- well, first of all, let me

ask you this: On the ones that are possible, what do you believe the pharmacist should do?

A That would depend completely on the pharmacist's judgment and situation of which we haven't really -- these are hypotheticals, of course, in very broad terms, and it doesn't talk about the specific information that the pharmacist has available right in front of them so --

Q Let me ask it this way: Should the pharmacist resolve the red flag before -- or the possible red flag before dispensing the drug?

A That's where the judgment comes in, and in many times resolving -- I believe in red flags. I mean, that's kind of the bottom line here is the concept of a red flag is very appropriate, I think we all agree on that. Having rigid limits utilizing red flags and denying or delaying prescriptions I don't agree with. And there can be examples where, in the possibles that were there, there can be examples where there's a red flag that you have some concerns about and you may not be able to resolve it for one reason or another --

Q Right, you said like maybe it's after hours and the doctor's not available.

A There may be times like that, and where I differ from --

Q So what ---

A -- Mr. Catizone is that's where I believe a pharmacist's judgment should come into play. There may be times when you cannot resolve a specific quote/unquote general red flag where they still should allow the patient to get it for patient safety. That's where we differ in some degree, and I -- and the examples would be things like maybe it's not a very big dose of medicine, but it exceeds what an arbitrary threshold might be, it might be just over some dose, it's not a large enough dose to cause harm, but if he can't get a hold of the doctor to verify that it's correct, to deny that patient that dose of medicine would cause harm, so I want the -- I want the pharmacist -- and luckily currently this is how they practice, to have judgment and have -- use their decision-making and the information that's available to them to do the best thing for the patient.

Q So if I'm running drugs and I've got the prescription or I'm diverting them, the secret under your plan is I just go after hours where they can't contact the doctor and the pharmacist can give it to me because the doctor doesn't answer the call; right?

A No. I don't think that's a very simple scenario at all.

Q All right. Spoiler alert, I'm going to get to your exam now, but this list of red flags that you're saying are

possible red flags and these statements about red flags that you weren't clear on -- or at least one of them -- they come from word for word from another expert hired by the defendants in this case.

10:16:56 Do you know Kimberly Burns?

A No, I don't.

Q She's their expert who's a lawyer and a registered pharmacist.

MR. MAJORAS: Objection, Your Honor.

10:17:06 BY MR. LANIER:

Q Have you read her report?

MR. MAJORAS: Can we go to the headphones?

THE COURT: I'll sustain that statement. You can certainly ask a statement, Mr. Lanier.

10:17:15 BY MR. LANIER:

Q Yeah. Have you read her report?

MR. MAJORAS: Objection, Your Honor.

THE COURT: Overruled.

MR. MAJORAS: Can we go to the headphones, please?

10:17:22 MR. LANIER: Please don't clock my time on the headphones.

(Proceedings at sidebar.)

THE COURT: All right. What's the objection?

10:17:32 MR. MAJORAS: We have not called Ms. Burns and

it's not clear that we will call.

THE COURT: It doesn't matter. He can -- Mr. Lanier can ask this witness what if anything he did to prepare or work or do his expert report or prepare for testimony. If he says no, he says no. If he says yes, well, then, we'll see.

MR. MAJORAS: Well, and I think he should be asked, first of all, whether he's even see the report because I don't know that that was asked.

10:17:56 THE COURT: That was the question. That was the question. Has he seen or read the report. That was it.

MR. MAJORAS: Okay.

(In open court at 10:18 a.m.)

BY MR. LANIER:

10:18:06 **Q** I'll repeat the question. Have you read her report?

A I don't believe so.

Q Because I've got your report and I read all of the different things that were supplied to you by the legal teams that represent these defendants.

10:18:21 To your memory, you were never supplied the report of Kimberly Burns, Registered Pharmacist, JD?

A Yeah, I apologize, I don't recall. I'd have to -- I could look at my report to see if it's on the list, but I don't recall the information.

10:18:42 **Q** And then my last review questions before I get into

your road map, you said lots of good things about opioids.

Fair?

A Fair.

Q Now, you know the plaintiffs, the people in these counties we represent, they're not saying all opioids are bad.

10:18:54

You understand that; right?

A I don't know what people have been testifying. I apologize.

Q Well, you've read our reports.

10:19:04

A Yes, I've read your reports.

Q Yeah. You've -- you know our witnesses.

You said you knew Joe Rannazzisi; right?

A I don't know him personally, I'm familiar with comments that have been presented in front of me, some of his excerpts.

10:19:19

Q So is it a surprise to you that we're not saying all opioids are bad? Does that surprise you?

A No, it shouldn't surprise me.

Q Do you believe there's been an opioid epidemic?

10:19:35

A I believe there's an illicit opioid epidemic currently.

Q Do you believe there has been a prescription opioid epidemic in the United States of America at in point in time since the year 2000?

10:19:50

A I believe that has been described as an opioid epidemic, yes.

Q So we have had a prescription opioid epidemic in this country, according to you as well; right?

10:20:05 **A** We have. I would state that it has changed and since prescribing ---

Q Sir, I'm not asking you that. Please hang on to my questions. Please.

MR. MAJORAS: Objection to the interruption,

10:20:18 Your Honor.

THE COURT: Overruled.

BY MR. LANIER:

Q Did you see the numbers in these counties of overdose and deaths?

10:20:25 **A** I believe I have seen those.

Q You have?

A I believe so.

Q Then we'll talk about those later.

All right. Here's your road map. I've got three

10:20:39 things I want to talk to you about, or I've divided it up into three areas.

The first is who you are. I'd like to get into it in a little more detail. Okay?

The second is vision limits, and by that I mean what

10:20:53 you've looked at and what you haven't. Okay?

And then the third thing I'd like to talk about is the bigger picture. All right?

Are you with me?

A I am.

10:21:07 **Q** Let's start with who is Robert Wailes.

Now, I got your CV when it was handed to me yesterday as you started to testify; right?

Do you remember that?

A I don't remember you being handed the CV.

10:21:34 **Q** I got handed one. You may not have been looking.

But I also downloaded your CV from the internet from your pain clinic you run; right?

I'm assuming you keep that one accurate; don't you?

A It's not as up to date as the one that was presented

10:21:53 in this case.

Q I'm going to show you demo Number 76. It is what's listed on your website for your pain clinic as your CV.

Do you have 76 in front of you?

A I believe. . .

10:22:23 **Q** Does that look like your CV as the founder, co-owner, and medical director of your pain clinic?

A I believe so.

Q By the way, we've heard a lot about pain clinics in this trial, some of them even back used to dispense the

10:22:46 opioids themselves in your pain clinics.

Did y'all do that in your pain clinic?

A For about two years we did for Workers' Compensation patients on a very small basis.

Q So yes?

10:22:56 **A** Yes.

Q Okay. Just curious.

So you've got what is basically a 2-page resume. I guess it sort of goes on to the third page or 2-page CV; is that right?

10:23:08 **A** I believe so.

Q And then you've got research publications down here.

Do you see those research publications?

Do you see it -- do you see that section?

A I don't have that on my --

10:23:33 **Q** Down on the bottom of Page 1.

A No, I don't have that.

THE COURT: I don't either, Mr. Lanier.

THE WITNESS: I don't have it.

MR. LANIER: CT exhibit demo 76.

10:23:48 MR. MAJORAS: Correct.

THE COURT: It's not on the one I have, so it's probably not on the witness's either.

BY MR. LANIER:

Q I'll put it up on the screen in the interest of time.

10:24:04 Do you see this?

A I do.

Q Research publications.

Do you see that?

A Yes.

10:24:12 **Q** Occipital Nerve Stimulation For the Treatment of Intractable Chronic Migraine Headache, a feasibility study.

Do you see that as well?

A Yes.

Q Now, you did not right that, did you?

10:24:35 **A** I was a co-author on that article.

Q No, sir, you were not. You swore under oath in this trial you were, in your deposition, you said, I was one of the co-authors; right?

A Yes.

10:24:47 **Q** I've got the article, sir. We'll mark the article as CT demo 75.

If we could pass that out, please.

Do you have that article in front of you?

A Yes, I do.

10:25:14 **Q** Let make sure it's the same. Occipital Nerve Stimulation For the Treatment of Intractable Chronic Migraine Headache: ONSTIM feasibility study.

Do you see that?

A Yes. This is not the article I was co-author in.

10:25:33 **Q** It's what?

A This is not the article I was co-author in. This is an article by Joel Saper, who's a headache specialist, but he's not an interventional pain medicine physician like myself. This is a different article.

10:25:46 **Q** Well, if you'll look, this is the one that's listed on your CV, isn't it?

A It may have used the same title, but this is not the article that I was co-author for.

Q Well, actually, that's on Page 2 of your CV, where it

10:25:59 continues. It is the Saper article. It's the exact same article. And you didn't write it, your an investigator, one of many; right?

A I have to apologize. I did not put that on the CV myself on the internet, and that's why it's not included in

10:26:19 the CV that was presented at this trial, and that appears to be a mistake.

I have seen the article that I'm a co-author on. It's not in the journal Cephalalgia, and so my associate who put together the website and wanted to be comprehensive about my

10:26:34 work appears to have made a mistake.

Q Tell us where your article is published. What peer-reviewed journal.

A I apologize, I don't specifically remember the name of the journal, but it was a -- it was a headache journal. It

10:26:49 was not Cephalagia, and I apologize.

Q But you've got one publication to your entire 37-year history.

Can you not remember where it was published?

A I'm not a research specialist and so --

10:27:04 **Q** That wasn't my question.

A So the answer is no, I actually do not know the name of that periodical.

Q But the article that you got on the internet on your CV is certainly not one you were an author of.

10:27:21 Fair?

A It appears that that's accurate.

Q No. It appears that it's accurate that you got something false on your CV; right?

A The CV on the internet, which I didn't testify to

10:27:32 during the deposition, is --

Q Well, it's not just on the internet --

MR. MAJORAS: Objection, Your Honor.

THE COURT: Hold. Hold it. Hold. Let the witness finish his answer and then you can ask another

10:27:42 question.

THE WITNESS: -- appears to -- I'm sorry.

THE COURT: You may finish your answer.

THE WITNESS: -- appears to have a mistake.

BY MR. LANIER:

10:27:47 **Q** And this isn't just on the internet, this is on the

website for your pain clinic information about we can go get your CV; right?

A Yes. I believe what you're saying is you got this off the internet.

10:27:59 **Q** I got it off your website.

A I understand what you're saying, yes.

Q I mean, this isn't like cruising through the mysteries of the web. This is go to your pain clinic, look you up and see what it says about you.

10:28:15 Do you understand?

A I understand.

Q And what it says about you, it's got everything you've done. It just gives you research publications you didn't write; correct?

10:28:26 **A** That is a mistake, that's correct.

Q And the one that you are claiming under oath to have written and published in a peer-reviewed journal, you just don't remember what it was?

A That's correct.

10:28:38 **Q** I'm sure we'll find it and I'll get to ask you on redirect. Let's keep going about who you are.

I took your CV and I compared it to Carmen Catizone's.

You read his report, didn't you?

A Yes.

10:28:59 **Q** You read his CV, which was attached to his report,

didn't you?

A I glanced at it.

Q It's pretty impressive, isn't it?

A He has a lot of history.

10:29:11 **Q** Oh, no, it's not just that, I mean, look, do you see all of his presentations?

MR. MAJORAS: Objection. Scope.

THE COURT: Overruled.

THE WITNESS: Again, I glanced at his CV. It

10:29:24 had quite a few entries.

BY MR. LANIER:

Q Standard of Regulatory Approach Presentation at the Virginia Board of Pharmacy.

Have they ever invited you to speak?

10:29:33 **A** No.

Q Understanding Corresponding Responsibility and Red Flags in Pharmacy Cases, presentation at the DEA Federal Pharmaceutical Drug Investigation and Prosecution Training.

Have you ever been asked to speak there on red flags

10:29:51 and corresponding responsibility?

A No.

Q The National Heroin Task Force Subcommittee Meeting in DC.

Were you asked to speak there?

10:30:02 **A** No.

Q The Prescription Opioid Abuse, Misuse and Diversion, Try Regulator Collaborative Boards of Directors Meeting that had the Federation of State Medical Boards, National Association of Boards of Pharmacy, and National Council of State Boards of Nursing.

Were you asked to speak there?

A No, sir.

Q Expert testimony. Has the United States ever called you to be their expert witness?

A No, sir.

Q In fact, you're testifying against them by these -- two of these same pharmacies have hired you in Florida to testify, haven't they?

A I am working on another case in Florida.

Q Yeah, against the government; right?

MR. MAJORAS: Objection, Your Honor. Headset, please.

(Proceedings at sidebar.)

MR. DELINSKY: Your Honor, fair cross is fair cross, but stating inaccuracies is not.

THE COURT: Well, let's -- well, I don't know what the facts are here.

MR. DELINSKY: There's no case by the --

THE COURT: Hold it. Hold it. Hold it.

Mr. Lanier, you asked the question. What's the case

you are cross-examining on?

MR. LANIER: There's a Florida case that he has issued a report on against, I believe is the DEA is the branch of the government.

10:31:21 MR. DELINSKY: False.

MR. MAJORAS: False.

MR. LANIER: I'll put the report.

THE COURT: You represented a case. Is there a case been filed?

10:31:28 MR. LANIER: Your Honor, yes. He's issued a report. He's gone against Professor Doering's opinions.

THE COURT: I just want to know, what is the case.

MR. DELINSKY: It's the A.G. case, Your Honor.

10:31:40 It's the Florida State A.G. case against the Walgreens and CVS. It's not by the United States. It's not by DEA.

THE COURT: Well, it's a state -- all right. Then you've got to clarify the question. If it's the State of Florida against some of the pharmacies, then you can't

10:31:50 represent it has the U.S. Government or DEA.

MR. DELINSKY: And, Your Honor --

MR. LANIER: And then that's fair, Your Honor.

THE COURT: Hold it.

MR. LANIER: I'll clarify it.

10:31:57 THE COURT: So let's just get the facts.

MR. LANIER: I had said against the government. I'll make it clear. I mean, the government of the State of Florida.

MR. DELINSKY: Okay. But, Your Honor --

10:32:02 MR. MAJORAS: He stated the United States Government.

MR. DELINSKY: Your Honor, that corrects the misstatement. It does not address the 402 and 403 --

THE COURT: Well, Mr. Lanier, will just say I

10:32:14 made a mistake.

MR. DELINSKY: No, but, Your Honor, there's a -- there's a deeper issue here --

THE COURT: What is the deeper issue?

MR. DELINSKY: -- which is whether the state

10:32:22 A.G. of Florida has brought a case against CVS and Walgreens is irrelevant and it's prejudicial.

MR. LANIER: Not when they bring the same expert and he's issued a report there, and I've got his opinions in those reports and it bears --

10:32:35 THE COURT: Hold it. Hold it. Hold it.

I'm not going to allow Mr. Lanier to get into any allegations in this case. But the fact that this witness has been hired by the defendants to represent them or to testify for them in a case brought by the State of Florida,

10:32:52 that's relevant.

MR. DELINSKY: All right. We object to that, Your Honor. We ask for a curative instruction -- or a limiting instruction as to the purpose for which that can be used and a corrective instruction on the United States issue.

10:33:03

THE COURT: Well, first, Mr. Lanier is going to correct the question. All right? He'll simply just say, I misspoke. Here's the case, and if you want, what do you propose I say?

10:33:10

MR. DELINSKY: Well, Your Honor, I want to think about it, but I will say this --

THE COURT: Well, think about it, and then --

MR. DELINSKY: No, Your Honor, I'm not done yet. I will say this for the record. Florida has become a hot-button issue in this case.

10:33:16

[Court reporter clarification.]

MR. DELINSKY: Over our -- over our objection. It is -- what has come in about Florida to begin with has been extraneous and now it's being compounded.

Your Honor, this is --

10:33:28

THE COURT: Mr. Delinsky --

MR. DELINSKY: -- we are in the land --

THE COURT: Mr. Delinsky, you all called this witness, okay? You had him do a whole lot of testifying. This is fair cross-examination. You should have known it

10:33:36

was going to come up. I'll instruct the jury that they can -- you want me to say they can consider it on bias? You tell me what you want to say and I'll consider it. Until now -- until then, I'm not going to say you anything. You propose something.

10:33:56

MR. DELINSKY: We will draft a limiting instruction.

THE COURT: All right. Fine.

MR. WEINBERGER: Your Honor, can we --

10:33:59

MR. DELINSKY: Over -- but our objection stands.

THE COURT: I'm moving on. I'm moving on.

MR. WEINBERGER: Your Honor, can we begin to take --

10:34:03

THE COURT: I've moved on.

MR. WEINBERGER: Can we keep track of the time, please?

(In open court at 10:34 a.m.)

BY MR. LANIER:

10:34:17

Q Sir, let me be clear. I say government, the government brought it. It's the State of Florida. That's the government. It's the state government of Florida. I don't want there to be a misunderstanding that I'm talking about the U.S. Government. Okay?

10:34:29

MR. DELINSKY: Objection, Your Honor.

THE COURT: Overruled.

BY MR. LANIER:

Q You've been hired by two of these pharmacy, Walgreens and CVS; is that right?

10:34:35 **A** I believe so.

Q So CVS and Walgreens have hired you in the State of Florida to issue opinions very similar to the ones that you've issued here; right?

MR. DELINSKY: Objection, Your Honor.

10:34:46 THE COURT: Overruled.

THE WITNESS: Can I -- I have a question. I have some confidentiality agreements with the case. Am I -- I'm not sure if I'm able to talk about that or not.

10:35:00 THE COURT: Okay. Well that's your answer then.

BY MR. LANIER:

Q Congressional testimony by Dr. Catizone, on and on and on for pages.

10:35:10 Have you been ever asked to give Congressional expert testimony on the issue -- on any issue?

A No, sir.

MR. MAJORAS: Your Honor, I object to the continuing reference of Dr. Catizone. He's Mr., he's not a

10:35:25 doctor.

MR. LANIER: He has an honorary doctorate, Your Honor. I think that's clear on the record. It's been said.

MR. MAJORAS: Honorary doctor?

10:35:29 THE COURT: Let's go with Mr. Catizone. All right?

MR. LANIER: And I'm fine doing that.

BY MR. LANIER:

Q You were just calling him Catizone. I just hate to do

10:35:37 that. Mr. Catizone.

Is that fair?

A That's fair.

Q He's worked with the DEA.

Have you ever worked with the DEA?

10:35:48 **A** Only through the Medical Board of California investigations.

Q Testified on behalf of -- well, I -- that's getting redundant. Hold on.

His chapters he's put in books and articles, have you

10:36:12 done any of that, other than that one article you don't remember?

A Is it possible for me to refer back to that article for just one moment?

Q To your article?

10:36:25 **A** Yes.

Q Well, just answer this question first. I'm sure we'll have a chance to dig out the other article later. I want to get the one that's the right one for you to look at, but let's look at this, chapters and books and articles.

Do you have any?

10:36:39

A Again, I'll -- I still have one article. It's not the one presented to me, but my name actually is in that article.

Q Oh, yeah. I -- I said to you that --

10:36:52

A I don't have any other articles.

Q Demonstrative 75, you're listed in the back -- first of all, authors are listed on the front, and that's a big prestigious deal, isn't it?

A I understand.

10:37:06

Q And authors have to give all of their conflicts and potential conflicts; right?

A Usually.

Q Authors get credit for that and get to list it on their CVs; correct?

10:37:18

A I understand.

Q And you're here in the back under acknowledgements. It's the little back section right before the references.

Do you see that?

A I understand that. And I would say that any research

10:37:37

study has multiple different publications that result from

the research, and this was one of those that I was not directly involved in the article.

Q The authors acknowledge the contributions of the investigators who participated in the study, and -- along with all of these other folks, you're listed, Robert Wailes; right?

A Yes.

Q But that's not an author, those are the author's acknowledging you and a bunch of others who contributed data for their paper; correct?

A That's correct. It was another article that I was co-author on.

Q Yeah. We'll find that and talk about it.

Now, another big difference between you and Mr. Catizone -- and so we're clear, master of science, registered pharmacist, and a doctor of pharmacy.

Do you see that?

A I do see that.

Q The other difference between you and him is he came in here and he was charging 300 bucks an hour; right?

A I don't know that, but I believe you.

Q Yeah. And you're -- you said yesterday you were basically 14 hundred bucks.

Is that a day?

A $1,395 for witness testimony an hour.

Q An hour. So you make over 10 grand a day doing this?

A If I testify for that long, I would.

Q So -- well, let's compare you to another doctor.

You know Dr. Lembke; right?

10:39:28 **A** I know who she is.

Q You saw her expert report, didn't you?

A Yes, I did.

Q You got a chance to see our addiction specialist and her opinions; right?

10:39:39 **A** Yes, I did.

Q And you saw attached to that report her CV, which was demonstrative 18 for the jury; right.

And she's -- it's pretty impressive too, isn't it?

A She has an impressive CV.

10:40:03 **Q** I mean, this is someone who's at Stanford University School of Medicine.

That's a good medical school, isn't it?

A Yes, it is.

MR. MAJORAS: Objection to continuing to march

10:40:13 through other's CVs.

THE COURT: Overruled.

BY MR. LANIER:

Q She teaches at Stanford University. That's a good -- that's a notable position, isn't it?

10:40:22 **A** That's an important academic position.

Q And not only that, she does clinic work there.

Did you know that?

A I was aware that she does some -- some part of her career a clinic.

10:40:36 **Q** Oh, yeah, she sees patient routinely.

Did you know that?

A I do now.

Q Ad hoc manuscript and report review.

Did you see all of the different journals that turn to her for her expert opinion and her expert work on the state of knowledge?

A I have scanned that.

Q And you say that you know what you know because you go to these important continuing medical education things and the drug reps come into your office and that's where you get your new knowledge; right?

A That doesn't state my source of information. I have 37 years of practice and experience and a wide variety of educational exposures, a wide variety of studying and work to educate myself and to be up to date. I spend a lot of time at different meetings and working with different colleagues and people around the country and keep up to date in many different ways.

Q But the ones you mentioned when you were being quizzed by the Walmart lawyer, Mr. Majoras, was you do a continuing

medical education and the drug companies send people into your office with lunch; right?

A I don't understand your question.

Q That's what you mentioned for your up-to-date training.

MR. MAJORAS: Objection. Misstates.

THE COURT: Overruled.

THE WITNESS: I don't believe I was limiting myself to those two types of education. I --

BY MR. LANIER:

Q Good.

A I don't recall that --

THE COURT: Hold it. Hold it, Mr. Lanier.

MR. LANIER: I'm sorry, Judge.

THE COURT: Let the doctor finish his question.

MR. LANIER: Yeah, I need to put my glasses on so I can see him. I'm sorry.

THE WITNESS: I don't recall that being the entirety of a response to an open-ended question about what is my exposure to continuing medical education.

BY MR. LANIER:

Q Because I'm hoping you're reading some of these journals that Dr. Lembke is making sure have good articles.

A We have different specialties, and so there would be

some crossover, but I do spend a lot of time reading journal articles.

Q And her scholarly work, have you bothered to read any of her books?

10:42:58 **A** I have not read any of her books. I have read part of that first one that you just highlighted, but --

Q Drug Dealer M.D.: How Doctors Were Duped, Patients Got Hooked and Why It's So Hard to Stop, you read part of that?

10:43:11 **A** Yes.

Q You knew some of the people in that, didn't you?

A Not directly. I don't remember who -- which people you're referring to. I don't know.

Q Well, you've got some good experience with

10:43:22 Purdue Pharma yourself beyond what you've already testified to, don't you?

A Not significant, no.

Q You understand we've got their records too?

A Absolutely.

10:43:36 **Q** All right. We'll deal with that in a little bit.

Have you gone to any of the peer-reviewed courses that Dr. Lembke has led on Prescription Drug Misuse and Addiction, Tapering Patients Off of Chronic Opioid Therapy?

Have you done to any of those?

10:43:59 **A** I haven't been to any of those Stanford courses, no.

Q Have you been to -- have you read any of her peer-reviewed original research articles?

A I don't believe so.

Q Even the ones that are relevant to what you do, like Use of Opioid Agonist Therapy -- oops -- for Medicare Patients?

Didn't bother to read that one?

A Oh, there's many different articles related to that. We have a world of literature, and I did not read that particular article in 2013.

Q But just for your own practice, though, have you read about Reasons For Benzodiazapine Use Among Persons Seeking Opioid Detoxification?

Have you read about that?

A Not that -- the answer is yes, I've read about that, but not that particular article.

Q All right. And so we're clear, you do have opioid addicts at -- in your pain clinic as patients, don't you?

A We have a small percentage of patients that have a diagnosis of opioid use disorder, yes.

Q Um-hmm. And even beyond the official diagnosis, you have other people that are clearly opioid dependent, don't you?

A Opioid dependence is a medical condition, as I discussed during my testimony, and that does not reflect

addiction. Opioid dependence is a completely different concept and the two should not be confused.

Q All right. In the interest of time, sir, let me finish with Dr. Lembke real quick.

10:45:26 MR. DELINSKY: Your Honor, I would object and ask that Dr. Wailes be given the opportunity to complete his answer.

THE COURT: Well, I think he did finish that answer.

10:45:32 Did you finish your answer?

THE WITNESS: That's fine.

THE COURT: Okay. That's what I thought.

BY MR. LANIER:

Q Peer-reviewed book chapters, other publications, 10:45:42 invited lectures all over the world on this stuff, you've never come across Dr. Lembke in any way other than the limited stuff you've told us about thus far?

A That's correct.

Q And she doesn't charge $1,400 or 1,395 an hour, she 10:46:01 was $500 an hour.

Did you understand that?

A I'm learning that right now.

Q Okay.

MR. LANIER: Your Honor, this is a good time 10:46:10 for the break.

THE WITNESS: Okay. I was going to suggest one.

MR. LANIER: Thank you, Judge.

THE COURT: Ladies and gentlemen, we'll take our usual mid-morning break, usual admonitions and then we'll pick up with Dr. Wailes.

(Jury excused from courtroom.)

THE COURT: Did someone say something?

COUNSEL EN MASSE: No.

(Recess was taken at 10:47 a.m. till 11:04 a.m.)

COURTROOM DEPUTY: All rise.

(Jury returned to courtroom.)

THE COURT: Please be seated.

And, Doctor, you're still under oath.

Mr. Lanier, you may continue.

MR. LANIER: Thank you.

BY MR. LANIER:

Q To keep us oriented, we're still asking about who is Robert Wailes. All right?

I want to discuss more of who you are.

I know you said you charged about 200,000 so far. I don't know that I've seen all of those bills, but I did see one bill. It was Exhibit 1 to your deposition, for $95,000; is that right?

A Yes.

Q Is this a correct copy of that bill?

A I believe it reflects my billing, yes.

Q Yeah. It's interesting. Your bill was submitted by IMS Consulting & Expert Services. Persuasion strategy. Expert witness. Jury consulting. Trial graphics. Trial presentation.

Do you see that, sir?

A I do.

Q Is IMS Consulting & Expert Services a point of contact for you in this case?

A Yes, it is.

Q I had a chance to go on their website.

Have you ever been on their website?

A No, I have not.

Q Okay. Did you know they hold themselves out as consultative trial and expert services?

Did you know that?

A I'm not really familiar with their background.

Q Did you know that -- well, first of all, that wasn't my question.

My question was, did you know they hold themselves out as consultative trial and expert services?

A I'm not familiar with that term, so I guess I'm not familiar.

Q Did you know they claim to have 20,000-plus cases

spanning practices with 95 percent of their business coming from repeat clients?

Did you know about that?

A No, I don't.

11:08:32 **Q** Nobody indicated to you if you do well, you might get repeat business?

A That hasn't been part of my exposure to them.

Q Did you know that they have an entire group dedicated to persuasion strategy?

11:08:52 **A** No, I'm not familiar with that.

Q That they do mental mining strategy sessions to create our, quote, story, closed quote for the jury.

Did you know about that?

A Not familiar with that.

11:09:10 **Q** Did you know that they claim to work with you and your experts formulate the best strategy for structuring reports and trial testimony?

Did you know about that?

A They have had no interaction with me on my work in this case other than billing.

11:09:30 **Q** Other than what?

A So I'm not -- other than billing. I am not familiar with any of that.

Q So did you really prepare those slides yourself?

11:09:41 **A** Yes, those are -- that's my -- that is my work.

Q So I could give you a computer and you could -- I could pull up PowerPoint and you could reproduce some of those technical slides with the graphs and all by yourself?

A I've had some assistance with those, but that's my work.

Q Okay. Well, now, wait a minute. I've had some assistance with those, or I do those by myself?

A I did not do those by myself. I directed all of those by myself. That's information directed by me.

Q Our jury consulting team assists with witness preparation so opinions are communicated clearly.

You've prepared for this, haven't you?

A Are we still talking about IMS?

Q Yes, sir, I read that from that -- yes, sir.

A They have not had any training or service to me regarding my testimony or report.

Q So have you done any preparation for testifying before you got here?

A Yes, but not through IMS.

Q Do you know who it was in the room with you?

A Yes.

Q And there were no jury consultants at all?

A I'm not sure what you're asking. I'm sorry. It kind of vague.

Q Our graphic -- back to IMS.

Did you know their graphic designers create graphics for both the report and trial that assists witnesses with teaching and persuading factfinders?

Did you know about that?

11:11:21 **A** I was not aware about that.

Q Their work on how to appeal to jury emotions.

Did you know about that?

A I have no exposure to that.

Q Their ability to enhance the clarity and confidence of

11:11:33 expert witness testimony at trial.

Did you know about that?

A Again, I have had not had any exposure to that from IMS.

Q So you just have them send out your bills and they pay

11:11:48 you and that's it?

A No. That doesn't state my relationship with them.

Q Well, I mean, this is your bill, isn't it?

A That's actually not my bill, that's reflective of my billing, I believe, but that's not my bill.

11:12:11 **Q** Who did you give your time to?

A The process is I fill out an Excel spreadsheet with the hours that I've worked and my charges and then I send that Excel spreadsheet with my charges to IMS.

Q Okay. So you send to IMS how you get your -- however

11:12:33 much money it is, and then these expert witness persuasion

tragedy folks submit.

Does it -- does payment come straight to you or does it go to IMS first?

MR. STOFFELMAYR: Judge, may we have a sidebar, please?

(Proceedings at sidebar.)

MR. STOFFELMAYR: Judge, Kaspar Stoffelmayr for Walgreens.

The parties, in the Motion in Limine stage, stipulated that there would be no reference in front of the jury to parties' or counsels' use of jury consultants, mock juries or related trial resources.

If this is permissible, I want to talk about Mr. Lanier's shadow jury.

MR. LANIER: Well, Your Honor, first of all, you won't find my shadow jury in here. I don't have a shadow jury in here. I have nothing like that.

MR. STOFFELMAYR: They're not in the room. We know that.

THE COURT: Well -- well, I --

MR. LANIER: I've just got -- I'm asking this guy. I haven't gone into those questions. I haven't asked him about the lady who's sitting back there. I have --

THE COURT: Right. Right. Right. Right.

MR. LANIER: I don't plan on it.

MR. STOFFELMAYR: He's made 20 references to -- not 20 -- he's made five references to jury consultants who have nothing to do Dr. Wailes.

THE COURT: Well, I don't know what they do. It's very unusual that this man's billing goes through someone else, and I think it's fair cross-examination.

MR. STOFFELMAYR: It would be fair if every question didn't use the word "jury consultant" when the parties have stipulated that that's of limits.

THE COURT: All right. All right. I agree.

MR. LANIER: I'm almost through with this, Judge. I'm moving on.

THE COURT: I think we have had enough. You've made your point --

MR. LANIER: Yeah, I agree.

THE COURT: -- Mr. Lanier. So let's move on from this.

(In open court at 11:14 a.m.)

BY MR. LANIER:

Q So the last question was, does the money come straight to you or does it go through IMS?

A I'm not sure exactly where that's coming from, but I send my bill to IMS, then I believe they charge the clients, the attorneys involved in the case or their -- who they're representing. I believe IMS gets paid, and then I believe

IMS sends a check to my office.

Q Okay. Let's go back in time a little bit, please.

By the way, historically, how many of your patients, percentage, if you can do, are end-of-life cancer patients?

11:15:30 **A** That's varied throughout my career and I can't give you a specific percentage based on any data that I can pull out. I don't have that data at the top of my head, but it was more common early in my career and a little bit less common now.

11:15:48 **Q** What about -- give me an idea back in the early 2000s.

A It would only be an estimate, but maybe 10 percent of my practice.

Q Did you know -- you're familiar with a company called Cephalon, right, or it's Cephalon.

11:16:20 How do you pronounce it?

A I think it's Cephalon.

Q Cephalon. Sorry. You're familiar with that company, aren't you?

A I have -- I have heard of it, yes.

11:16:28 **Q** Well, not just I have heard of it. You know them, don't you?

A I wish I could say I know them better, but they've interacted with my practice, but I -- I'm guessing I'm going to hear my history about what they've done with our practice.

11:16:45

Q Well, did you know they considered, back in 2003, their relationship to you to be important and that you were one of their target physicians in 2003?

MR. MAJORAS: Objection. Foundation.

11:17:00 THE WITNESS: Yeah, I'm --

THE COURT: Overruled.

THE WITNESS: I'm not aware of being a target physician. I'm not familiar with that term, but I suspect that -- yeah, I'm just not familiar with that term.

11:17:15 BY MR. LANIER:

Q Did you know they maintained records on you noting you are a big golfer.

Are you a big golfer?

A I enjoy playing golf, like many other people.

11:17:27 **Q** And this drug company Cephalon, they make an opioid -- make opioid products, don't they?

A I suspect they do.

Q No, you don't suspect they do, you know they do, don't you?

11:17:43 **A** I apologize. I don't know the exact product line that Cephalon has. I'm sure they have a product line. I apologize, I don't know it.

Q Well, are you -- you are familiar with ACTIQ, A-c-t-i-q, aren't you?

11:18:02 **A** Yes.

Q The lollipops?

A Yes.

Q Made by Cephalon?

A Thank you.

11:18:08 **Q** You didn't know that?

A I could not pull that off the top of my head, no.

Q Did you know that you were one of their top 10 prescribers of ACTIQ back in 2003?

A Was not aware of that.

11:18:22 **Q** That they list you with 43 percent of the market share back in 1983?

MR. MAJORAS: Objection.

BY MR. LANIER:

Q And I'm sure that's in your area.

11:18:33 THE COURT: Overruled.

BY MR. LANIER:

Q Did you know that?

A Yeah, I don't know at all what 43 percent of what denominator. So no, I'm not aware of what that means.

11:18:41 **Q** But you know that you would not be using ACTIQ properly under the FDA if you were giving it to people who were not dealing with breakthrough cancer pain and already tolerant to opioid therapy; right?

A I am aware of that indication.

11:19:08 **Q** And yet my question to you, sir, under oath, did you

ever prescribe ACTIQ to a patient other than a -- someone trying to manage breakthrough cancer pain already receiving intolerant to opioid therapy?

A I think that's very likely that I used the medication what we call off-label, which we do for many different medications.

Q So that I've got a chart I can refer to later, ACTIQ, that's the drug we're talking about, and it's like a little lollipop on a stick; right?

A Yes.

Q Except that lollipop has fentanyl, one of the most potent opioids as you've already testified; right?

A Correct.

Q And the FDA made it real clear that this is indicated only for the management of breakthrough cancer pain in patients with malignancies -- malignancies is cancer; right, tumors?

A Yes.

Q Who were already receiving intolerant to opioid therapy; right?

A Yes.

Q Now, that is not just the FDA approval for ACTIQ back when you were prescribing it, but that's in what's called a black box warning; right?

A I believe so.

Q In other words, it's front and center, that's what it was approved for; correct?

A I believe so.

Q And yet you would prescribe ACTIQ for reasons not approved by the FDA, wouldn't you?

A I used it off-label is what we call it, and there were probably circumstances where that is true.

Q When you say I used it off-label, that means you used it for something it had not been approved for by the FDA, doesn't it?

A In the regular of course of a physician's practice, this is not uncommon to use a well-known medication for other applications than the specific research showed FDA approved indications.

So, yes, I did use it off-label. An FDA drug can be used off-label --

Q That wasn't my question, sir?

A -- in the appropriate way.

Q Yeah. My question was not is it appropriate to do it and are you going to go to jail. My question was --

MR. MAJORAS: Objection, Your Honor.

THE COURT: Overruled.

BY MR. LANIER:

Q My question was, when you say I used it off-label, that means you used it in a way it had not been approved for

use by the FDA; correct?

A Yes.

Q Thank you.

Now, did you know that Cephalon, this company, who made this wound up having to enter a plea with the government for off-label marketing and pay a hefty fine?

Did you know about that?

A I was aware they did get in trouble for some type of problem. I'm not familiar with the specifics of it.

Q They allegedly promoted the drug for noncancer patients used for such maladies as migraines, sickle cell pain crisis, injuries, and in anticipation of changing wound dressings or radiation therapy?

If that is the truth, sir, you were one of the physicians who was actually prescribing it for some of those reasons, weren't you?

A I don't recall specifically prescribing it for those reasons, but my guess is they were in trouble for their marketing efforts and not for the actual use of the medication, but they probably got in trouble for how they promoted it.

Q Yeah, they pleaded guilty for promoting it off-label, which is the kind of usage you had with it, isn't it?

A Some of my usage could have been off-label, yes.

Q Okay. Now, that's -- we started that question with me

asking you if you knew whether or not you were listed as one of their top prescribers in an important relationship to maintain abid call for all of that.

Remember?

11:24:59 **A** Yes.

Q But that's not the only opioid company that you've done work with -- or that you've been important to.

Is that fair?

A I'm sure I'm important to many different companies.

11:25:07 **Q** Well, you're familiar with the drug Duragesic, aren't you?

A Yes.

Q Duragesic is another opiate, isn't it?

A Yes.

11:25:23 **Q** It's made by Janssen, a division of Johnson & Johnson; right?

A That's my understanding.

Q And what kind of opiate is Duragesic?

A It's fentanyl. It's a fentanyl patch.

11:25:39 **Q** It's a fentanyl what?

A Patch.

Q Whether you talked about fentanyl yesterday, you told us it was typically in a patch; right?

A Yes.

11:25:47 **Q** Did you mention the lollipops that you were -- that

you and I were discussing a few minutes ago yesterday?

A I didn't mention that because it's a very small part of the use of fentanyl. It's mostly --

Q Today it is, but back in the early 2000s when you were using it quite a bit it was a lot more prominent, wasn't it?

A Duragesic has always been the primary way to provide fentanyl products. It's a patch for 3 days, and it's always had the biggest market share, I'm sure.

Q Now, Duragesic, the fentanyl patch by Johnson & Johnson -- well, by Janssen, one of their companies -- aren't there two S's in Janssen? I think so.

A I'm not sure.

Q All right. I'm putting it in there. I may be wrong.

You were -- well, early today you were asked did you have any funding relationships with any of the opioid questions.

Do you remember those questions?

A Yes, and --

Q Did this one slip your mind?

A It may have. I suspect I'm going to learn something about it. The only thing I didn't say that I did reveal in my deposition, and I've thought about since you asked that question, is we did have some educational programs and some of -- during the early 2000s, I believe, and some of those educational programs probably got some partial funding from

pharmaceutical companies.

Q Yeah, it's not just that, you were specifically a Duragesic speaker. For example, you did a speaking engage at Tri-City Medical Center March of 2004.

11:27:41 Do you remember that?

A Not specifically, no.

Q No memory of being a Duragesic speaker?

A Not specifically.

Q Do you remember the idea that you were also recognized as a Duragesic advocate?

11:27:56

A I don't remember that term.

Q That they -- do you remember that for you to give the speeches they required -- they, the Janssen, the opioid company, required you to go through online training with them?

11:28:19

A Again, I apologize, I don't specifically remember, but that would be reasonable.

Q So it's possible that you were a Duragesic speaker, a Duragesic advocate, who did online training with the company and got paid to make speeches, including at the Tri-City Medical Center in 2004? Possible, you just don't remember.

11:28:40

Fair?

A Fair.

Q Now, you're not alone in your clinic. You've got other people who work there, right, and co-own it with you?

11:28:59

A Yes.

Q Am I correct that one of them is Jeremy Adler?

A Yes.

Q Is he a doctor?

11:29:19 **A** He has a doctorate degree, but he's a practicing physician assistant.

Q He's actually got a publication to his name, doesn't he, at least one?

A I believe he has published more than one article.

11:29:34 **Q** On Clinical Guidelines For the Use of Chronic Opioid Therapy; right?

A Yes.

Q Now, this gentleman, you called him a physician's assistant?

11:29:48 **A** Yes.

Q He also speaks or has been a speaker for Endo Pharmaceuticals.

Did you know that?

A I know that he works with some companies. I'm not familiar with what lectures he's actually given.

11:29:58 **Q** So your -- is he one of the co-owners? I don't remember what your answer was.

A Yes, he is.

Q So he's not a medical doctor, but he's still a co-owner of the pain clinic?

11:30:09

A That's correct.

Q And as one of your co-owners of the pain clinic has been given speeches or been retained by Endo to do work for them?

11:30:20 **A** I honestly don't know the relationship that he has with Endo.

Q But you do know that he's spoken for them before; right?

A I know that he does lectures. He does some lectures

11:30:30 and training for people.

Q And so we're clear on this relationship as well, Endo is an opioid manufacturer, isn't it?

A I believe so.

Q Well, you don't believe so, you know they are, don't

11:30:45 you?

A I apologize, I don't work with -- I don't have a great working knowledge with manufacturers on a day-to-day basis. I prescribe medicines, and it just doesn't cross my path very much. I'm sure in the past I've talked to many

11:31:01 different reps from different companies, and I probably know the rep names better than the company names, but clearly I've been exposed to these names and companies and drugs, and I apologize, I'm just not very conversive with it.

Q With all due respect, sir, you sought out Purdue and

11:31:19 asked them to hire you to be a speaker, didn't you?

A I have no recall of that.

Q Let me see if I can refresh your memory.

January 31st, 2011. Do you recall whether or not you, with the Foundation For Pain Medicine, were going to be a speaker at a February national leadership roundtable?

A I don't have a specific recollection for that. I'm not even sure of the organization, the Foundation For Pain Medicine?

Q Um-hmm. Yeah. That's what it was listed as.

A I may have had interaction with them. It sounds like it's perhaps part of another association or something. Foundations usually are charitable organizations that promote education, but I don't have any specific call of this.

Q Would you have any specific recall of why or how Purdue came to get your CV?

A No, but I think my CV's probably pretty readily accessible.

Q Yeah. And you don't have any recall yourself of seeking out speaking positions for Purdue or Endo?

A I don't have any specific recall of that at all.

Q Do you know Brett Michelin?

A That name is familiar.

Q Do you know Carol Lee?

A Yes.

Q Do you recall meeting with the Endo people with Carol Lee about whether or not e-prescribing can be a holdup for scheduled medications like C-IIs?

A I don't remember a specific meeting with that circumstance, but at least now I under- -- I know what organization we're talking about now.

Q Did you privately share with anybody that some of these pain society meetings need new speakers at the podiums, especially for the corporate supported symposiums?

A I don't have any recall of comments like that.

Q And do you recall whether or not you were lobbying for yourself to be one of the new speakers?

A I do not have any recall for that.

Q And you say you don't really know Endo.

Would you be shocked to find out that Endo claims they know you very well?

A No comment.

Q Okay. Now, I found this interesting in light of your Slide Number 4, what is a pain management specialist? And you said, compensation is not linked to opiate prescribing.

Do you see that?

A Yes.

Q Now, of course, you're familiar with a lot of pain clinics that were shut down by the government; right?

A I'm familiar with some, that concept, yes, absolutely.

Q Well, I noticed even one of the documents in your reliance materials was a PowerPoint by Joe Rannazzisi.

Do you remember having that in your materials?

A Yes.

11:35:36 **Q** And I think in that PowerPoint Mr. Rannazzisi talks about the migration of pain clinics from Florida over across into the California.

Do you remember that?

A I do remember seeing a slide with arrows to

11:35:49 California.

Q Yeah. Well, when you say compensation is not linked to opioid prescribing, would you agree with me that compensation is linked to patients coming in and using your pain clinic?

11:36:12 **A** Yes. We get paid for office visits and consultations and cognitive services as well as procedures, yes.

Q And I know that you said you have a really good reputation in the San Diego area; right?

A I believe so.

11:36:24 **Q** Have you looked at the internet reviews on you and your practice?

A I have not. Not recently.

Q Okay. So when you say you've got a good reputation, you're basing that on what people are saying to you?

11:36:37 **A** Yes.

Q Okay. But whether patients use your pain clinic, that is directly linked to compensation, isn't it?

A Not directly -- not directly linked to writing prescriptions, no.

11:36:54 **Q** That wasn't my question, sir.

Patients use your pain clinic, that's linked to compensation, isn't it?

A Correct. We get paid by seeing patients.

Q Here. We can do this real easy.

11:37:10 You've got a pain clinic and people go into that pain clinic; right?

A Yes, they do.

Q And something happens before they leave, and that is they get examined and treated and maybe has a prescription

11:37:41 issued and they pay for the visit somehow. Fair?

A That's correct.

Q And so the more people that go in, or the more often they go in, the more you make. True?

A That's correct.

11:38:04 **Q** Now, at this point in our United States of America a lot more attention is paid when it comes to prescribing opiates; right?

A Yes, that's true.

Q And so if you were going to give opiates, you do what

11:38:24 you call closely monitor; right?

A Yes.

Q So you write these opioid prescriptions and you tell these people that if they're going to give the opioid prescriptions, you've got to see them again, and again, and again, don't you?

A All of our chronic pain patients, whether they receive opiates or not, have regular office visits, yes.

Q But with the opiates, they don't just have regular office visits, they've got a lot of other things you do as well.

You do the urine test, you've got to do all these other things; right?

A They -- we do urine testing, but I don't know what you mean by all these other things.

Q Well, you talked about --

A They're not income producing other things.

Q So y'all do the urine test for free?

A No, I said other things -- we don't do other things for -- collect income. We have a small fee, I think it's $8 or something, for the urine test because we send it out, so that's a handling charge. But there's not other things that we're deriving income from on our regular office visit patients.

Q And as these patients come in and become, what did you call it, instead of addicted, you called it opiate

dependent?

MR. MAJORAS: Objection. Misstates the testimony.

BY MR. LANIER:

11:39:49 **Q** Well, that's what I'm asking. Is that what you called it?

A I'm not sure what -- your foundation of the question. Could you repeat it?

Q Yes, sir. That was good legal terminology there, 11:40:00 foundation.

Opioid dependent, is that the word you used right before our break?

A I have said opiate -- we've talked about opiate dependence, yes, we have.

11:40:15 **Q** And you've got a lot of patients who are opiate dependent, don't you?

A We do have many patients that are opiate dependent, yes.

Q And by opiate dependent, it means they've got to get 11:40:27 their opiates; right?

A Excuse me, one more time.

Q And so you've got a lot of people that just keep coming back, and back, and back, don't you?

A Yes. We have a lot of our patients come back and see 11:40:41 us on a regular basis.

Q So when you say compensation is not linked to opioid prescribing, maybe it might be fair to say you're not getting a cut of each opioid prescription that gets filled, but there's certainly a link, isn't there?

11:41:01 **A** Very indirectly because we don't have any difference in pay whether we prescribe an opioid or not.

Q Well, if you prescribe Advil, do they have to come back over and over to get the Advil prescription?

A It depends on the severity of their problem. If they

11:41:17 have a severe problem, they may not tolerate opioids or whatever. We see -- all of our -- not 100 percent, but most of our chronic pain patients we need to see on a regular basis for more than just prescriptions.

Q Wasn't my question, sir. Can you answer my question?

11:41:32 **A** Is we may need to see patients even on Advil on a regular basis.

Q You may need to. There's a difference between may need to and must, isn't there?

A Yes.

11:41:45 **Q** You don't have the same follow-up with patients that you say, hey, take some Advil, make it a prescription level, 800 milligrams, okay, go take some Advil and come back and see us if you don't feel better in a couple of weeks.

A That doesn't reflect my practice. I understand what

11:42:07 you're alluding to. In my practice, we don't typically see

patients who just need Advil and can come in when necessary. That would be more of a primary care practice scenario. Patients that we see are typically much more severe and need regular follow-up and maintenance.

11:42:26 **Q** Look, I'm not fussing that. Almost all of yours need opiates; right?

A Not all of them, no.

Q Most of them do, don't they?

A The majority do.

11:42:42 **Q** All right. We're almost through with the first stop, but we got a few more things we got to clarify.

Let's try and get through this stop before lunch. Okay?

A Okay.

11:43:04 **Q** You talked yesterday about your important role with the American Association of Pain Management; right?

A No. It's --

Q You didn't?

A No.

11:43:20 **Q** AAPM. What does that stand for?

A It's the American Academy of Pain Medicine.

Q Oh, okay. My mistake. Let me get it right.

AAPM is the American Academy of Pain Management?

A Medicine.

11:43:46 **Q** Medicine. Thank you.

All right. And you talked about how notable it was that you're a trustee or something?

A I'm on their board of directors.

Q Board of directors.

11:44:02 And you have been a member for how long?

A Since the early 1990s.

Q And how long have you been active in it?

A I've been more involved with leadership over the last 10 years.

11:44:22 **Q** Okay. So you know Phillip Saigh, S-a-i-g-h?

A Yes.

MR. LANIER: Plaintiffs' Exhibit 21857, can we pass that out, please?

(Brief pause in proceedings.)

11:45:14 BY MR. LANIER:

Q Do you have that, sir?

A Yes, I do.

Q I think this is just one example of something that you might have been involved in, I don't know. It's an e-mail

11:45:24 from Phil Saigh to a number of others about the AAPM delegates to the AMA dinner.

Do you see that?

A I'm just looking at it now. I'm trying to read what it says.

11:45:45 **Q** Do you recall it, now that you're looking at it, sir?

A I. . . don't recall the specific e-mail, but I remember -- I think I recall the circumstance.

Q Well, and so that I'm not playing gotcha, you are one of the recipients of the e-mail?

11:46:06 **A** Correct.

Q You're not fussing the e-mail for the content thereof; right?

A No, not at all.

Q All right. So you were involved in 2011 at least

11:46:16 going to some of the dinners. Is that fair to say?

A There was at least one dinner here that I was involved with.

Q I'm assuming it wasn't the only one. Didn't you go to other dinners?

11:46:28 **A** This is, I think, the first year that I probably started getting involved and it was 10 years ago.

Q All right.

A So. . .

Q And in that regard were you a member of the AAP --

11:46:50 well, let me ask it this way: Mr. Majoras, lawyer for Walmart, asked you about Purdue.

Remember those questions?

A I believe so, yes.

Q And he asked you whether or not Purdue had ever

11:47:08 supported some of your entities or some of the things that

you were affiliated with.

Do you remember that as well?

A I don't remember the specific contest, but Purdue has definitely been a supporter for the American Academy of Pain Medicine.

Q Well, not just a supporter, your American Academy of Pain Medicine, in 2001, wrote a letter to the DEA about Purdue.

Did you know about that?

A I'm not familiar with that.

Q Do you know whether or not the AAPM, your AAPM, ever told the federal government that Purdue is one of the most ethical pharmaceutical companies in the United States?

MR. MAJORAS: Objection.

May I be heard, Your Honor?

(Proceedings at sidebar.)

MR. MAJORAS: Your Honor, my issue here is that Mr. Lanier is just asking questions without any foundation whatsoever, and in particular, I believe he's referring to a document in this most recent line of questions that dates back to 2001, yet he's referring to 2011 when Dr. Wailes was there. And it's an inappropriate question.

THE COURT: Well --

MR. LANIER: Wailes was there.

THE COURT: Well, hold it. If this document is from 2010 or '11 on when the doctor said he's been in leadership, I think that's fair. If it's something from 2001, I think it's not relevant.

11:49:02 MR. WEINBERGER: Your Honor, Mr. Majoras put up a slide touting the fact that he was a member of the AAPM without any limitation whatsoever, and then --

THE COURT: Well, let me see -- let me see -- what is the argument -- what is the foundation for this

11:49:21 question?

MR. LANIER: The foundation for this, Your Honor --

THE COURT: It started with an e-mail 21857. That's 2011. This something else.

11:49:32 MR. LANIER: This is something totally different, Your Honor.

THE COURT: Let me see the basis of it.

MR. LANIER: Okay. Let me hand it up to you.

MR. MAJORAS: But his testimony is he's not

11:49:37 familiar with this.

THE COURT: Well, I want to see what it is.

MR. MAJORAS: May I see it too, please? Your Honor, I'm not sure what's been handed up.

MR. LANIER: It's the 2001 you were talking

11:49:56 about.

MR. MAJORAS: Thank you.

MR. LANIER: Yeah.

Your Honor, I don't mean to interrupt your reading, but I'd like to say something when you're done.

11:50:31 THE COURT: Well, tell you what, this is the way to do this, rather than -- you know, show him the article and ask him, as now one of the leaders, does he agree with it.

MR. LANIER: That's great. I'll do it that

11:50:48 way.

THE COURT: Just do it that way. I read it, and, you know, I think then that's a fair way to do it.

MR. LANIER: Okay.

MR. MAJORAS: May I get a copy, Your Honor?

11:50:54 THE COURT: I thought you had one.

MR. MAJORAS: I don't.

THE COURT: Make sure Mr. Majoras has a copy of this.

(In open court at 11:50 a.m.)

11:51:07 MR. LANIER: And we'll give the witness a copy as well, Judge.

BY MR. LANIER:

Q All right. You got 20 -- Plaintiffs' 28217 in front of you.

11:51:46 Do you have it, sir?

MR. MAJORAS: I ask that it not be displayed until foundation is laid, Your Honor.

THE COURT: All right.

BY MR. LANIER:

11:51:55 **Q** Do you have Plaintiffs' Exhibit 28217 in front of you, sir?

A Yes, I do.

Q And you'll see it's on American Academy of Pain Management letterhead.

11:52:03 Do you see that?

A Yes, I do.

Q And you recognize that, don't you?

A No. That's not the organization I'm a member of.

Q The American Academy of Pain Management?

11:52:14 **A** That's -- I'm not a member of that organization.

Q The American Academy of Pain Management is different than Pain Medication?

A Yes. They're two different organizations. They're completely different.

11:52:31 **Q** Have they ever been related to each other?

A No. No. They're -- no, they've never been related, and American Academy of Pain Management is no longer in existence.

Q Were you ever a member of the American Academy of Pain

11:52:46 Management?

A I believe in the 1990s it was one of the first organizations, and I initially did join it, yes.

Q And were you a member for how long?

A I don't remember. It was a brief number of years.

11:53:01 **Q** Well, I mean, were you a member in 2001 -- I mean, we can go back and look. We've got the membership roles.

Were you a member?

A I do not recall.

Q Do you recall if you were a member when they ceased to

11:53:16 exist?

A No, I was not a member then.

Q Do you recall why they ceased to exist?

A Not being a member, I'm not completely sure. So I guess I can't claim knowledge of that.

11:53:29 **Q** All right. That's fair enough.

So I go back to my time line of now we're in the 2011/2012/2013 timeline, go fast-forward 10 years from that document.

MR. STOFFELMAYR: Judge, could we have the

11:53:47 slide fixed since that quote comes from a different organization?

THE COURT: That slide should come out.

MR. MAJORAS: A different organization, different quote, everything, Your Honor.

11:53:53 THE COURT: All right. Mr. Lanier, please

take the slide down.

MR. LANIER: Well, this is not -- oh, I see, the Purdue. Yeah, that does not -- let's. . . there we go.

BY MR. LANIER:

11:54:09 **Q** So we're going to stick with the American Academy of Pain Medicine; okay?

Do you recall if while you were active, since 2011, if at any point in time, maybe November of 2013, you applied to become a clinical investigator for Purdue Pharma?

11:54:37 **A** I don't remember the specifics of that.

Q Don't remember the specifics, or do you remember at least generally applying to be an investigator for Purdue Pharma?

A I do not recall that, no.

11:54:57 **Q** American Academy of Pain Management -- no, Pain Medicine. Got to get it right.

Ms. Lanier and Ms. Fleming, would you y'all please pass out Plaintiffs' Exhibit 18314.

I'll represent to you, sir, this is United States

11:55:42 Senate committee on finance record.

Do you have it in front of you?

A Yes, I do.

Q Are you familiar with the investigation behind opioid manufacturers' financial relationships with groups including

11:56:11 the American Academy of Pain Medicine?

A I'm not sure which investigation you're referring to. I know that's come as an issue regarding Purdue Pharmaceuticals, yes.

Q Well, if you will look on Page 28 of this document, you will see a chart for the American Academy of Pain Medicine.

Do you see that?

A Yes, I do.

Q And that is the American Academy of Pain Medicine of which you are on the board. True?

A Yes.

Q And in this investigation, it lists various companies that had given money to the academy of which you are leadership. True?

A Yes, I believe so.

Q And these are in your leadership years, but let's look at these and just look at how many of them were opiate companies.

Allergan, is that opiates?

A I apologize, I'm not very conversive about pharmaceutical companies and their medications, so I apologize, I'm not going to be able to --

Q Well, let's pick out the ones you certainly know,.

Cephalon, we have already discussed that; right?

A Yes.

Q 120,000.

Endo, we have already discussed that, 224,000?

A Yes.

Q Janssen and Johnson & Johnson?

11:58:01 **A** Janssen I'm familiar with. I'm not sure what the mother company Johnson & Johnson has.

Q But you understand that's the mother company; right?

A Yes.

Q So 83 and 7,500; right?

11:58:11 Looking at the next page, Purdue Pharma.

Do you see that, sir?

A I'm trying to get to it.

Q It's the very next page, Page 29.

A Yes, I see that.

11:58:41 **Q** And you know Teva to be also an opiate manufacturer, don't you?

A I believe so.

Q Yeah. So we start looking at how drug companies pumped almost $6 million into this entity over just that

11:59:00 time period, pursuant to the investigation of the U.S. Senate.

Do you see that, sir?

A I -- I see the charts and those numbers, yes.

Q And if you look at some more specific -- well, let's

11:59:23 do it this way. In addition to the money paid to that

entity, if we were to go through this report and look at the other entities -- by the way, did you know that before this report came out?

A I don't have any knowledge of the actual numbers and the cumulative amount. I was aware that our association, as all associations, seek funds from multiple different, call them vendors, people that are interested in our specialty and to exhibit at the exhibit hall and to help sponsor our educational function.

Q Yeah, so when we look at a document like you put in front of the jury yesterday, we've marked ours Plaintiffs' Exhibit 2999, but it had a different mark when you used it yesterday, the Joint Statement on Pain from the DEA, do you remember this?

A Yes, I do.

Q And this is something you cite and you had a slide to it. This was your slide. It was Slide Number 14. Focusing only on the abuse potential could erroneously lead to the conclusion these drugs should be avoided when medically indicated generating a sense of fear rather than a legitimate respect for their properties.

Do you remember that?

A Yes, I do.

Q And that was a joint statement between the DEA, but also 21 health organizations.

Do you see that as well?

A Yes.

Q Those health organizations included the ones that were being funded, by and large, or at least to a great degree, by the companies that made the opioids; right?

A I think the DEA would be an exception to that.

Q You think what?

A I think the DEA was not receiving funds from the opioid manufacturers.

Q Oh, I'm not fussing that point. I'm talking about the 21 health organizations, American Pain Society.

You know who they were, don't you?

A Yes.

Q They were tight, tight, tight with Purdue Pharma, weren't they?

A Again, I think most pain organizations received funding from multiple sources, including many of them Purdue Pharma.

Q American Pain Foundation, tight with the opioid manufacturers; right?

A Again, I don't know the exact relation, but, again, I'm assuming that most pain organizations, to support their educational meetings and all that, recruited funds from a number of different pharmaceutical companies, including Purdue.

Q $5 million to the American Academy of Pain Medicine over less than a decade.

Y'all must have tremendous educational programs.

A That supports a lot of meetings. The meetings are very expensive, and yes.

Q And then at these meetings you've also got money coming from the drug manufacturers, don't you?

A I think you need to be more specific in that question. I'm not sure what you mean.

Q Well, did you know, in 2001 and -- hold on.

Did you know Jeff Engle?

A That rings bells.

Q Now, Purdue was I think even throwing money into the California Medical Association where you are, right?

A It's possible. Again, every medical organization seeks funding for their programs and pharmaceutical companies are frequent funders for educational programs.

Q So -- sorry. So if we look at Plaintiffs' 21873, would you agree with me that -- getting this out -- that the drugs companies aren't just funding this for nothing, they expect to get something out of it; right?

A They want something out of it, yes.

Q Yeah, they want -- they want close touches with you prescribers, don't they?

A They want to get their name out there as advertising,

I believe.

Q Well, it's not just that. They want -- they want to have VIP seats; right?

MR. MAJORAS: Objection, Your Honor.

12:04:13 THE COURT: Overruled.

THE WITNESS: I'm not sure how to answer that.

BY MR. LANIER:

Q All right. Let me ask it this way: Take a look at 21873. This is your American Academy of Pain Medicine. It's on your website where you're on the board of trustees.

12:04:23 Do you see that?

A You're referring to the website? I have a document in front of me. What -- I'm not sure what you're saying.

Q I pulled this off the website. It's the section on how to be a corporate supporter of your American Academy of Pain Medicine.

12:04:40 Do you see that?

A I see the heading on it, and it's not part of the website I would frequent, so I have not seen this before.

Q Well, you're on the board of directors. See if this information seems foreign to you or if it reflects the policy.

12:04:54 AAPM offers opportunities to engage leaders in pain medicine, untrue?

A You're read that from someplace, I'm sure.

12:05:18

Q But is it factual, sir? Is it an accurate reflection of the truth?

A I'm sorry. Could you repeat the question?

Q Yes. Does the AAPM offer opportunities to engage in leaders in pain medicine to corporate supporters?

12:05:31

A At some broad indirect level, yes.

Q Are there ways to reach your audience, including advertising in your eNews, the Academy's official newsletter?

Do y'all offer that opportunity?

12:05:51

A That's probably one of the opportunities they have.

Q At the annual meeting do you offer commercial opportunities and pre-conferences that includes satellite symposia, sponsorship, supporting fellows and residents to attend the meeting and exhibit? True?

12:06:12

A That sounds like our educational sessions.

Q And via the corporate relations council, have you ever served on that?

A No, I have not.

Q Benefits of participating in the corporate relations council on various levels include special meetings with AAPM leaders.

12:06:24

Have you had special meetings with these opioid manufacturers?

A I don't believe so, but again, I'm not one of the

12:06:40

leaders, per se, but I'm on the board of directors.

Q Invitations to the AAPM president's reception.

Have you ever been to the AAPM's president reception?

A Yes, I have.

12:06:53 **Q** Did you see the opioid manufacturers there?

A I have no specific recall. They're rather large receptions.

Q Opportunities for visibility and communication.

Those opportunities may be there, but you're saying

12:07:09 you've just never seen them?

A I'm not saying that. I'm saying I have no specific recall of seeing them at a large reception.

Q And I asked you about VIP seats because of this slide -- I mean, this page. That highlighter is mine, by

12:07:21 the way. It was not highlighted on the web. I don't want to misrepresent that.

But you see those VIP seats?

A Yes, I do.

Q Throughout the year, AAPM offers year-round

12:07:34 opportunities for supporting various programs and initiatives.

Do you see that?

A Yes, I do.

Q The corporate relations council. Reserve your seat.

12:07:54 Benefits of partnering with AAPM offers many opportunities

to interact with the leading pain physicians and clinicians of pain management treatment teams.

Do you see that?

A Yes, I see this.

12:08:08 **Q** This is a format for establishing and building relationships.

Do you see that as well?

A Yes.

Q And then we have the corporate relations council of 12:08:25 the American Academy of Pain Medicine partners in seeking new advances in the specialty of pain management and optimum quality of life for pain patients. The council enables you to connect in a more significant way with the leaders in pain management.

12:08:42 I'm basically almost through with this, but do you see that as well?

A Yes, I do.

Q And you can do it on different levels, the premier level, or the associate level; right?

12:08:51 **A** Yes.

Q And that's where you'll find companies, including Teva, whom you know to be an opiate company; right?

A Yes.

Q And that's still today going on, isn't it?

12:09:04 **A** I believe so.

MR. LANIER: Your Honor, I lost track of time, and I apologize, and I apologize to the jury.

THE COURT: Well, I didn't want to cut you off in the middle but this is a good place to stop.

12:09:12 MR. LANIER: You're very kind, Judge. I'm sorry, and I'm sorry to the jury.

THE COURT: Ladies and gentlemen, we'll break for lunch until 1:10, usual admonitions apply, and then we'll pick up with the balance of the doctor's testimony.

12:09:25 (Jury excused from courtroom.)

(Recess was taken at 12:09 p.m.)

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AFTERNOON SESSION

(In open court at 1:12 p.m.)

COURTROOM DEPUTY: All rise.

(Jury returned to courtroom.)

13:13:50 THE COURT: Okay. Please be seated.

Doctor, you're still under oath.

And, Mr. Lanier, you may continue, please.

MR. LANIER: Thank you, Your Honor.

May it please the Court, ladies and gentlemen. . .

13:14:04 BY MR. LANIER:

Q Sir, I think the jury may have heard a reference, some may already know, what PubMed is.

A Yes.

Q Do you know?

13:14:15 **A** Yes, I do.

Q PubMed is the database of medical publications; right?

A It is a database for medical publications.

Q And you can type in a name of an author and pull up any publications by that author. True?

13:14:28 **A** It doesn't contain all publications, but it does contain most publications, yes.

Q Did you have a chance over lunch to go to PubMed and to look up, or did you remind yourself of your article?

A I did not personally look it up over lunch.

13:14:46 **Q** Okay. Do you remember now what your article was or

where it was published?

A I have no further recall from what I discussed before.

Q Okay. That's all I was checking.

A couple other things to clean up.

13:15:00 I want make sure the record is right. When we looked at Plaintiffs' Exhibit 18314, which was the money that was contributed by all these different opioid companies to your pain -- American Academy of Pain Medicine, I forgot to note for the record this important footnote, that during final

13:15:27 stages of the committee's investigation -- to make it big enough to read, I'm going to have to do some movement here -- AAPM provided additional data showing millions of dollars in additional payments from opioid manufacturers to AAPM and an affiliated entity, the American Academy of Pain

13:15:50 Medicine Foundation.

So in addition to the nearly 6 million AAPM received directly from opioid manufacturers, the organization reported 1.1 million in revenue from the foundation during those years 2013 to 2017?

13:16:13 Do you see that as well?

A Yes, I do.

Q And then the data shows the foundation got a million dollars in payments from opioid manufacturers from 2013 to '19.

13:16:26 Do you see that also?

A I do.

Q Now -- a second matter to clean up.

That dinner that we talked about you going to, Plaintiffs' Exhibit 21857, remember the dinner?

13:16:50 **A** I remember the e-mail that you showed me.

Q Right. You did not remember the dinner.

Here's what I failed to point out. And Dr. David Haddox, do you know him?

A I -- acquainted with him, yes.

13:17:09 **Q** Yeah, this fellow who's doing the dinner things with y'all is with Purdue. He was a vice president for Purdue, wasn't he?

A I knew he was somewhere up in the organization of Purdue, yes.

13:17:24 **Q** So the dinner that your AAPM delegate dinner with the AMA is one that Purdue's going to be at, vice president it seems.

Does that ring a bell to you as to whether or not you remember the dinner?

13:17:40 **A** Vaguely, yes.

Q Now, in your slide presentations to this jury you gave this slide about your qualifications. It was Slide Number 2.

Do you recall that?

13:17:59 **A** I do recall that.

Q And that is a slide which says you are a board-certified pain management doctor; correct?

A That's correct.

Q So we're clear, you list that on your CV as well, don't you?

A Yes.

Q In fact, your CV -- I'm putting up demo 76 -- has three different boards that have certified you; is that right?

A That's correct.

Q The American Board of Pain Medicine. That's your AAPM that we've been talking about; correct?

A It's an affiliate with the AAPM.

Q And then you claim on your resume, on your CV, to be board-certified by that other group that you have slightly familiarity with and don't know if you've got anything to do with them now or not.

Remember?

A I recall that, and they were the first pain organization to have a board certification in the early '90s, and that was the first test that was available, and so I did take that test and join their organization.

Q So you still have it on your CV?

A Yes.

Q This is what you post on your website?

A Yes. I'm still officially certified with them even though the organization itself is no longer present.

Q So you've got a board certification that you advise on your website that doesn't even exist anymore?

13:19:43 **A** The company that initially gave that to me no longer exists.

Q So you're board-certified, does it -- with someone who is non-existent?

A Concurrently non-existent.

13:20:04 **Q** You understand the California Medical Board has rules of ethics, right?

A Yes.

Q And you understand those rules of ethics have to do with how you advise in your web space, doesn't you?

13:20:15 **A** Yes.

Q And you know it's no small thing to put something false on your web space. Don't you?

A I'm sure that's true.

Q In fact, it's an ethical violation, isn't it?

13:20:27 **A** It would be -- false advertising is not good.

Q Well, not only not good, it's subject to sanctions; right?

A It may be.

Q No, not may be, it is; isn't it?

13:20:37 **A** I don't -- I'm not certain of that, but I would not be

surprised.

Q So you've got a resume telling me come see me because of who I am that lists an article that you're not an author on and that claims to be board-certified by an entity that doesn't even exist anymore; right?

13:20:58

A That is true. The article I still -- I apologize, that's not the right article. I still recall of being an author, not the first author, but an author on an article regarding the same subject.

Q Do you remember your PubMed login where I could put it up here and we could all login together to PubMed and type in your name see if anything comes up?

13:21:16

A I go to PubMed easily just by going to PubMed.

Q You don't have to log in. So we could --

Rachel, my iPad is right down there.

13:21:38

So we could go up here, and what do I type in, what are we looking for, PubMed?

A Yes.

Q And you spell your name R-o-b-e-r-t, W-a-i-l-e-s; is that right?

13:22:26

A Yes.

Q Now look what it pulls up. It pulls up that very article where you're not an author but you're listed as a collaborator because you're part of the investigation team, Robert Wailes.

13:22:47

Do you see that?

A Yes.

Q Not an author, are you?

A Not in this, no.

13:22:54 **Q** Found one result for Robert Wailes, and is it still your testimony under oath that you're published somewhere with another article of this study?

A I believe so, yes.

Q Okay. Now, on the board certification issue, before 13:23:19 we leave that, there is an organization that crosses all of the medical professions that certifies people for a board certification; right?

A I believe so.

Q You're familiar with the American Board of Medical 13:23:47 Specialties?

A Yes.

MR. LANIER: Rachel, would you please pass out 21871 and 21872?

BY MR. LANIER:

13:24:24 **Q** Do you have those in front of you, sir?

A Yes, I do.

Q 21871 is a general page that gives information about the American Board of Medical Specialties.

Do you see that?

13:24:40 **A** Yes.

Q Higher standards. Better care. And that's what's generally meant by board certification in the medical world.

Fair?

A Correct.

13:24:49 **Q** And those people board-certify in a lot of different areas, that's Plaintiffs' Exhibit 21872, and these are the different areas where you can get board-certified like most doctors mean when they say they're board-certified; right?

MR. MAJORAS: Objection to form as to what

13:25:14 other doctors mean.

THE COURT: Well. . . all right. Sustained as to form.

MR. LANIER: Okay.

BY MR. LANIER:

13:25:21 **Q** In your medical parlance that you commonly use or hear others use, the idea of being board-certified in the general broader medical community is talking about someone with a board certification by the American Board of Medical Specialties; right?

13:25:41 **A** In general that's true. In California, they actually do certify other boards as well.

Q Okay. That's fair.

Now, there's a whole different area -- areas where someone can be board-certified; correct?

13:25:59 **A** Yes.

Q And you have one of those board certifications, don't you?

A Yes, I do.

Q That's your American Board of Anesthesiology with the subspecialty certification that I've highlighted in blue; right?

A That's correct.

Q But these other things that you list as a board certification, these are, shall -- well, let's go to the first one. This is just kind of its own certification within the organization. It's not accredited certification by the American Board of Medical Specialties; true?

A It is recognized throughout the country in many states, and the state of California recognizes it as a scientifically based and valid board certification.

Q That wasn't my question, sir.

I said that's not part of the American Board of Medical Specialties that board certifies doctors; right?

A That's correct.

Q Thank you.

And then the other one, of course, we've already covered. They don't even exist anymore; right?

A That's correct.

Q Before I leave the first stop, my last set of questions is hopefully pretty quick and simple.

We've talked about who you are. I'd like to now, before we move on, talk about who you are not.

Are you able to see that okay?

A Yes, I can.

13:27:43 **Q** You're not a primary care doctor, are you?

A No, I am not.

Q And you're not an emergency medical doctor; right?

A No.

Q You're not an urgent care doctor?

13:27:55 **A** Nope.

Q You're not a general surgery doctor?

A No, sir.

Q You're not an OB/GYN doctor?

A No, sir.

13:28:04 **Q** You're not an oncologist?

A Nope.

Q You're not hospice provider?

A No, sir.

Q You're not a dentist?

13:28:14 **A** I'm hospice provider. I have cared for hospice patients in the past as part of my practice, so I'm not a hospice specialist, but I have provided care for hospice patients.

Q Oh, and I bet you delivered babies while you were in

13:28:27 medical school at some point.

A No, this is during my practice in my career as pain management.

Q Yeah, and I'm not fussing that. I'm asking, is that your area of specialty? Are you a hospice provider?

13:28:39 **A** I am a hospice provider, I am not a hospice specialist.

Q Okay. All right. Yes. I'll put yes.

Are you a dentist?

A No.

13:28:50 **Q** Are you a podiatrist?

A No.

Q Are you a psychiatrist?

A No.

Q Are you a board-certified addiction doctor?

13:28:58 **A** No.

Q And I left one out. Are you a pharmacist?

A No.

Q So you testified in this area about the work that primary care doctors do, but you're not a primary care doctor. Fair?

13:29:33 **A** I am not a primary care doctor, correct.

Q And whether you testified about what emergency medicine doctors do, that's not you either; is it?

A I am not an emergency medicine doctor.

13:29:43 **Q** Whether you testified about what urgent care doctors

do, you're not one of those, are you?

A No, I am not.

Q All surgical specialties. I put general surgery. That's not you either, is it?

13:29:55 **A** I'm a surgical subspecialty.

Q Right, but all surgical specialties. That means are you -- do you do knee replacements?

A No, I don't.

Q Hip replacements?

13:30:07 **A** No, I don't.

Q Do you do herniated nucleus pulposis?

A Yes.

Q Okay. So do you do fusions or do you do laminectomies?

13:30:17 **A** Neither.

Q So when I say herniated nucleus pulposus, in terms of treating them as an orthopedic surgeon or neurologist, do you do that?

A Neurologist don't treat those.

13:30:30 **Q** Well, they do if they are in the neck.

Did you not know that?

A Neurosurgery does, not neurologists.

Q Neurosurgery is a type of --

[Court reporter clarification.]

BY MR. LANIER:

Q All right. And I apologize. Sir, I don't want to spend the time fussing over this. We can fuss about this outside.

13:30:43 But my question is, are you all surgical specialties?

A No, I am not.

Q And yet you testified about them too, didn't you?

A Yes, I did.

Q Are you an OB/GYN?

13:30:54 **A** No, I'm not.

Q And you testified about that, right?

A Yes.

Q You testified about oncologists, didn't you?

A Yes, I did.

13:31:00 **Q** Testified about hospice providers, of which you are one?

A Yes.

Q Testified about dentists and what they do. That's not you either?

13:31:07 **A** That's correct.

Q Testified about podiatrists and what they do. That's not you either?

A Correct.

Q Testified to some degree about psychiatrists, but

13:31:16 you're not one of those?

A That's correct.

Q Testified to some degree about board-certified addiction doctors, like Dr. Lembke. You're not one of those?

13:31:25 **A** That's correct.

Q Testified about pharmacists all day long, and you're not one of those?

A My opinions are based on the relationship between a prescriber and pharmacists.

13:31:34 **Q** Because what you are is you are a high-volume opioid-prescribing, pain clinic owning doctor from Southern California; right?

A No. In fact, we're famous for not being high volume. The fastest office visit we have is 20 minutes, so we are

13:32:10 not a high volume. We're actually known for being comprehensive care and not having a large volume of patients going through and see us.

Q So let me define high volume my way and see if I need to modify it on here. You tell me the right word.

13:32:24 Most of your patients get opioids, don't they?

A The majority of our patients do receive opioids.

Q So what would you call that if not high volume?

A I think the two are very unrelated. We take opioid prescribing very seriously. We're not a high volume

13:32:38 practice. We don't see people every 5 minutes, every

10 minutes, or even every 15 minutes. It takes time to do the type of practice that I aspire to.

Q How about high percentage?

A If you say a high percentage opiates, that would be accurate.

Q Okay. Because, I mean, you understand you got hired in this case, and you got hired in Florida, but there are a lot of doctors between Cleveland and California that got passed over to get to you; right?

A That's true.

Q And it's not because you've well-published in this field. You haven't published anything, have you?

A I'm not from the ivory tower, no. I'm a person who sees patients.

Q Well, so does the people who published, but I'm not -- I mean, you're not fussing Dr. Lembke sees patients multiple days a week, are you?

A I don't know her schedule.

Q Okay. Some doctors have time to see patients and publish, don't they?

A That's true.

Q Did it -- did you question why are you coming here to California to find me to testify about all of these different areas when I'm not one of those?

A I don't think this case is only about academic

opinions, and so I think I offer a different perspective.

Q You offer the perspective of someone who prescribes opioids and has done so for most of his life. Fair?

A I think my perspective also includes my experience with the Medical Board of California in looking at the standard of care as well as having national awareness of all the specialties at the house of delegates for the AMA as well as within my own specialty at the American Academy of Pain Medicine, so I'm offering --

13:34:32 **Q** With due respect, your California--

A Can I finish?

Q Oh, I'm sorry. I was -- I'm sorry. Go ahead.

A Offers me a perspective about my specialty throughout the entire country. And I've certainly met a lot of

13:34:47 doctors, especially from -- including from Ohio and the Cleveland Clinic specifically and it's been a good experience and provides background along with my 37 years of practice.

Q Great. And we're going to talk about some of those

13:34:59 Ohio doctors and see what you're familiarity is now as we move down the road. Okay?

A Okay.

Q So let's move from who is Robert Wailes to vision limits. All right?

13:35:28 Now, on vision limits, I've drawn up another little

road stop for us on it. I want to do two things. I want to talk about things that you've seen and relied on and things you have not seen and that's how we'll cover this vision limit stop. Okay?

13:35:50 **A** Okay.

Q All right. I saw in your reliance materials some DEA PowerPoints; fair?

A Yes.

Q I saw in your reliance materials that you've relied

13:36:02 upon some regulations. Fair?

A Yes.

Q I want to talk about what I did not see in your reliance materials with you. First of all, as a general concept, would you agree with me that it's important to get

13:36:17 data, to get information?

A I'm not sure the context of what you're asking about, but --

Q Almost any, but certainly if you're going to express an opinion you want to do your homework first, don't you?

13:36:32 **A** Information's important when providing opinions.

Q You don't go treat a patient without finding out who they are first; right?

A That's correct.

Q You don't treat a patient without doing an

13:36:43 examination, do you?

A That's correct.

Q You want to go to medical school before you practice medicine; right?

A Absolutely.

13:36:52 **Q** You want to train to do surgery before you do surgery; right?

A Yes.

Q So it's important to gather information before you come in for a chance to testify; right?

13:37:07 **A** Yes.

Q Now, during your information gathering you weren't making -- charging the 14 hundred or whatever it is an hour, it's less for that; right?

A Yes.

13:37:16 **Q** What was your hourly rate for your information gathering?

A $729.

Q 729?

A Yes.

13:37:27 **Q** Why don't you just do 750, 730?

MR. MAJORAS: Objection, Your Honor.

BY MR. LANIER:

Q You did 729.

THE COURT: Overruled.

13:37:36 THE WITNESS: Those are the prevailing rates

among colleagues of my in Southern California, and those have the been the rates I've had for quite a while and commensurate with other doctors I'm familiar with.

BY MR. LANIER:

13:37:51 **Q** 729 is the prevailing rate. Okay. So let's go through this and see what you didn't see. All right?

First of all, did anybody put handcuffs on you about what you could or couldn't see?

A No handcuffs.

13:38:06 **Q** Okay. So the world was open; right?

A I suppose so.

Q All right. But you never looked at Walgreens' policies, did you?

A Not specifically, no.

13:38:19 **Q** Before you came and testified about red flags, you never looked at Walgreens' company expectations on red flags, did you?

A Not specifically, no.

Q Before you came and testified about what is a red flag 13:38:33 and what's not a red flag, you never looked at Walgreens' company expectations on that, did you?

A No.

Q So if Walgreens lists --

MR. LANIER: Well, Your Honor, I'd ask to be 13:38:47 able to publish Plaintiffs' Exhibit 19616.

BY MR. LANIER:

Q Do you have a copy of Walgreens -- I mean, of Plaintiffs' 19616, sir?

A I believe so.

13:39:24 **Q** If you will look on the fourth page you'll see the start of the PowerPoint where Walgreens talks about good fate dispensing training.

Do you see that?

A Yes.

13:39:41 **Q** And this is all about prescription integrity.

Do you see that as well?

A I see that written on the page, yes.

Q And you can see from the front we're in the years 2017, so this is about 4 years ago, at least the e-mail to

13:39:56 which this is attached.

Do you see that?

A I see the e-mail address, yes.

Q And the timestamp on the e-mail; right?

A Yes.

13:40:03 **Q** If you'll look at Slide Number 10, which is Page 12 of the document, here are the company expectations for Walgreens.

In your groups, make a list of red flags that may indicate a prescription is not legitimate. You got

13:40:23 2 minutes. At the end of 2 minutes, be prepared to share

your list. This is a training session.

Do you see that?

A I see that, yes.

Q And then look at what the next slide is. Here are the company expectations.

13:40:33

Red flags.

Do you see those?

A I will soon.

Q It's Slide 11, Number 13 -- Page 13.

13:40:48

You got it? Do you have it, sir?

A Not yet, but I'm -- there's different page numbers on the paper and the slides.

Q Yes, it's Slide 11, it's Page 13.

Slide 11. Page 13.

13:41:13

Tell me when you're there.

A I see.

Q Do you see it?

A Yes.

Q All right. Now, in that regard, sir, look at what the company expectations are around red flags.

13:41:30

Do you see that?

A I'm looking at that now, yes.

Q And we can compare it with some of these that I pulled from a different document of an expert, but when you compare it, these are a lot of ones where you said possibly and even

13:41:53

not usually.

Do you see that?

A Yes. I don't --

Q So you disagree with Walgreens' training program where they are they're training their pharmacists that large quantities of prescription or large number of controlled substances prescriptions are a red flag, not possibly, they are.

You disagree; right?

A That's incorrect, and that misstates my testimony.

Q So do you agree?

A I've always --

MR. MAJORAS: Objection. May he finish?

THE COURT: Hold. Hold it. Let the doctor finish his answer. Then, Mr. Lanier, you can ask another question.

MR. LANIER: Yes, sir. I'm sorry, Judge.

THE WITNESS: I've been clear that red flags are appropriate and useful prompts, but not the Catizone red flags, and I've been specific about what objections I have with his red flags.

BY MR. LANIER:

Q Well, sir, this second red flag that is here is one that you were criticizing Mr. Catizone for, cocktails, opiate, benzodiazapines, and muscle relaxant combos.

Do you see that?

A I see that.

Q And that's one you criticized Dr. Catizone -- or Mr. Catizone over, wasn't it?

13:43:00 **A** Yes, for very specific reasons, and I would do it again gladly.

Q So when the company expects their pharmacists to recognize this as a red flag, you disagree with the company, don't you?

13:43:11 **A** No. That's out of context. Again, my objections with Mr. Catizone were not general red flags. My objection was his algorithmic -- the mechanical way that he approaches red flags and specifically on the trinity that he in his report said that it was no prescriptions for the trinity were

13:43:34 medically legitimate prescriptions, and I disagree with that. There are occasions where it is legitimate.

I disagreed that it has to be resolved -- in this particular case he has no resolution because he says no -- it's -- that it's not legitimate. So that's where we

13:43:52 differ. Is it a general red flag? Yes, it is. I think we're in agreement that many of these things should bring special attention for a pharmacist, and I support that.

Q So now you'll agree that all of these possibles are, in fact, red flags; you just challenge how you deal with a

13:44:12 red flag; right?

A In essence, yes.

Q So if we look at the testimony that's been offered in this case, for example, from Michelle Travassos with CVS, she testified in front of this jury, question: Every red flag that a pharmacist identifies --

13:44:29

MR. DELINSKY: Objection. Objection, Your Honor.

(Proceedings at sidebar.)

MR. DELINSKY: Your Honor, my understanding is that it has not been permitted to show witnesses testimony from earlier in trial. We have been abiding by that rule certainly with our -- with our own experts, and I believe that's the rule that's been followed --

13:44:48

THE COURT: He's not showing it. He can ask -- you can ask any witness whether you agree or disagree with what another witness said, and he said I agree or she's wrong.

13:45:02

MR. LANIER: And the whole reason that rule exists is so that you can't question people live without them having been prepped around this kind of stuff.

13:45:18

THE COURT: So it's a fair question. Said now, here's what so-and-so said, as long as that is what the person said.

(Simultaneous crosstalk.)

MR. DELINSKY: But, Your Honor, here's another

13:45:25

problem with it, it is -- this is horribly misleading out of context. Miss Travassos was crystal clear that there are potential -- there's a differentiation between red flags and then red flags. The rule CVS follows, and by showing one excerpt without the others is horribly misleading and inappropriate. That's why you don't ask witnesses about passages from testimony --

MR. LANIER: No. No.

MR. DELINSKY: -- that are stripped of their context.

MR. LANIER: Well, he can redirect, Judge, if I even remotely do anything wrong.

THE COURT: If it's -- you know --

MR. LANIER: I've got it, Judge.

THE COURT: I'm relying on both counsel to be honest about this.

MR. LANIER: Yeah. I've got it.

THE COURT: If not, you're going to be shown to this jury as being dishonest, and I don't think anyone wants that if you're a lawyer.

MR. LANIER: I got it, Judge. And I'll tie it in specifically to CVS's published red flags in just a moment.

(In open court at 1:46 p.m.)

BY MR. LANIER:

Q I'll represent to you that the question asked Ms. Travassos with CVS was, well, every red flag that a pharmacist identifies with a prescription must be resolved before the pharmacist can fill the prescription; correct?

13:46:54 Answer: Yes.

You disagree with Ms. Travassos -- Travassos, the witness for CVS. True?

A If that's how she feels absolutely, then that gives no judgment at all to the pharmacist, so I would disagree.

13:47:13 **Q** Well, of course it gives judgment to the pharmacist because the pharmacist can decide to do the due diligence and decide to resolve it; correct?

A They can do their best to resolve it, but there are times when they will not be able to resolve it if they can't

13:47:27 get all the questions answered.

Q And if they --

A And they won't have the same information that the prescriber has.

Q Yeah.

13:47:34 **A** The prescriber has all the medical background, the medical decision-making and all that before even writing the prescription, and if it's within the standard of care, and 99 percent of doctors or more are within the standard of care, if they cannot resolve it, then I think it should err

13:47:52 on patient safety. And that may mean, again, in the

judgment of the pharmacist, of providing the prescription.

Q Well, but --

A Or dispensing the prescription.

Q There's still judgment. If, for example, let's look at CVS's red flags that they publish in Plaintiffs' 15656.

BY MR. LANIER:

Q Have you got that, sir?

A I believe I have 15656.

Q Yeah. You'll notice on the very front it says awareness of red flags associated with the non-legitimate use of controlled substances.

Do you see that?

A Yes, I do.

Q And if you'll flip toward the back, it's got on Page 4 of the document, prescriber controlled substance red flags.

Do you see that?

A Yes, I do.

Q Prescription is written by a prescriber located outside of the pharmacy's local area. Red flag.

Do you see?

A I see that, yes.

Q Now, if Ms. Travassos is correct that a pharmacist should not be filling that until they resolve it, it doesn't mean that the pharmacist's judgment is gone, because you can ask the patient why they're traveling outside the local area

to visit the prescriber, can't you?

A That's possible, yes.

Q You can resolve this red flag by simple things like that and hear them say, I'm going to the Cleveland Clinic for a specialist?

A That's very appropriate.

Q And then you've resolved the red flag, you document it, you dispense the drug?

A Understood.

Q It involves discretion and judgment of the pharmacist, but you still resolve the red flag first. You see?

A In this case that you described it is, but what I was bringing up and my specific objection is not this, but rather when they cannot resolve it. That's the issue that I raise.

Q So when they ask the patient why are you traveling outside the local area and the patient says, uh, I don't want to answer that, you think, well, prescribe it, that's standard of care?

A See, there's not enough information to answer your question specifically. Obviously, I don't know what the case is or anything else, but I'm talking about those challenging cases where they've perhaps have talked to the patient and yet they need to speak with the doctor to get a better understanding of what's going on. And there are

cases where they may not -- and again, it's not this hypothetical that you gave me there because if they do resolve it, that's great. I'm talking about the cases where they can't resolve it.

13:50:59 **Q** You're talking about cases where individuals have been known to travel great distances to visit prescribers who are willing to write prescription for non-legitimate purposes.

Did you know that's happened?

A I'm aware that that's a -- definitely has happened in

13:51:14 the past, and the bottom line is some things -- again, I feel strongly that -- I'm -- the experience of pharmacists in my background, my experience and background, tells me that pharmacists are very diligent about looking at the prescriptions closely. But there may be circumstances where

13:51:33 they are not able to resolve it. And if they're not able to resolve any of their concerns or a hundred percent of their concerns, it's at that time that they need to use their clinical judgment.

Q And yet that's what Ms. Travassos for Walgreens, at

13:51:49 least said, was not the -- I mean, for CVS, at least, said was not the case. The rule is don't issue; right?

A We probably interpret that differently, yes.

Q Okay. And we can look at more of them. They -- but it's the same stuff. We could look at, you know, patient

13:52:13 insists on paying cash for controlled substances. Will not

use insurance even if available. You see?

A Again, that's a red flag.

Q And it's one that according to Ms. Travassos must be resolved to the satisfaction of the pharmacist and documented. Fair?

A I think the pharmacist should make every effort, absolutely. That's a good example of a red flag where the pharmacist should be able to get to an answer.

Q And -- all right. With that we look at CVS. Let's go back to Walgreens. Walgreens has these red flags that I've got up here.

Do you see that?

A Yes.

Q And I think Walgreens witness on this was Brian Joyce that the jury got to meet.

Mr. Joyce was asked, so it's a red flag that needs to be investigated and resolved before the prescription is filled; right?

Answer: Yeah.

You resolve these things before you fill them. Did you know that from Walgreens' perspective?

A Again, I would have to take it into context of the exact situation, and my objection is very specific. I'm happy to go through it again, but I understand Walgreens -- how you explain the testimony.

Q Well, not wanting to leave out Walmart. Tasha Polster from Walmart --

MR. MAJORAS: Objection, Your Honor.

MR. LANIER: I'm sorry, excuse me. My brain is fried, Judge. I'm going to hold on to that and wait in a minute anyway. I want to do something else.

BY MR. LANIER:

Q Sir, you didn't look at Walgreens' policies, you didn't look at Walmart's policies, you didn't look at CVS's policies. True?

A True.

Q You didn't look at the fill histories in this case that are relevant, did you?

A I'm not sure exactly what a fill history is.

Q Well, a fill history in the pharmaceutical world is which prescriptions did they fill.

Did you know they have to keep those records?

A I'm not familiar with the internal workings, so no, I was not specifically familiar with that.

Q Wait a minute. You've been testifying about the standard of care of pharmacists, and you did not know that they had to keep records of prescriptions they filled for controlled substances?

MR. MAJORAS: Objection. He's testified about the standard of care for physicians.

MR. LANIER: No, pharmacists.

THE COURT: Overruled. Overruled.

THE WITNESS: No, I have not been testifying regarding the standard of care for pharmacists. I am not a pharmacist, but I will testify to the relationship between a physician writing a prescription and a pharmacist.

BY MR. LANIER:

Q Sir, we've got your PowerPoint slides, and before I even go there, we've got your expert report.

In your expert report you opined on the standard of care of a pharmacist, didn't you?

A You'd have to point out that area specifically for me to comment on that.

Q Well, you wrote your report, didn't you?

A Yes, I did.

Q And do you recall commenting and having an opinion on the standard of care of pharmacists?

A Not specifically. I'm sure there may have been inferences, but I do not hold myself out as a pharmacist so I would not directly comment on that.

Q You surprised me on this one so I got to pull your report up.

I've got a copy, but it doesn't have a mark on it. Does anybody -- do -- I'll put it on the ELMO so everybody can see it on the Wolfe Vision.

Is this your report, Robert Wailes, M.D.?

A Yes, it is.

Q And this is the opinions you listed in your report?

A That's the first page of the index, yes.

13:56:37 **Q** And do you talk about how pharmacists are trained to evaluate prescriptions --

MR. LANIER: Your Honor, we'll mark this as demo 106.

THE WITNESS: Yes.

13:56:52 BY MR. LANIER:

Q But pharmacists are not, however, appropriately trained or well-positioned to assess whether a prescriber has prescribed any medication in accordance with then prevailing medical standard of care.

13:57:13 Do you see that as well?

A Yes. I'm very happy to discuss the medical standard of care.

Q So when you offer a report where you speak about these different aspects of pharmacists and their training and

13:57:37 their lack of training, is it safe to say you didn't even know what their training involves as far as keeping records?

A I actually specifically inquired as to their training, and so I am aware of their training requirements.

Q You --

13:57:57 **A** I'm very aware of --

THE COURT: Let the doctor finish his answer.

MR. LANIER: I'm sorry, Judge. I hear it and it short circuits.

THE WITNESS: And I'm very aware of physicians' training and what's required to be a physician, and I'm aware of the differences in our training and experiences that lead up to our professional roles.

And so my opinions come out of my medical expertise and the relationship between physicians and pharmacists.

BY MR. LANIER:

Q And in that regard -- well, let's just go back to where we were.

So you don't know that they have to keep records of fill histories?

A I don't have that information, no.

Q And I'm assuming did -- with all of your knowledge of Ohio doctors, pain doctors, did you do any research on Dr. Franklin?

A I did not do any specific research on Dr. Franklin.

Q Do you know of Dr. Franklin and his history writing opioid prescriptions in this area?

A I believe he was mentioned in one of the expert reports, but I don't have any recall specifically about what he did.

Q And so in the reliance materials you relied on you saw

a mention of him, but you don't recall what it was?

A I don't recall the specifics, correct.

Q Do you approve of a doctor who overwrites and overwrites and overwrites opiates?

13:59:25 **A** To answer that question I'd have to have more background information. I do review doctors for the medical board and I'm used to looking at those questions, but they do require a lot of investigation before making that determination.

13:59:36 **Q** And no one hired -- and no one saw fit to have you do that before you testified about what was going on up here in Northeastern Ohio. Fair?

A No, that was not my job to investigate Dr. Franklin.

Q How about Dr. Veres? Did you look at anything of

13:59:55 Dr. Veres?

A Same comments.

Q Same comments. So if he's overprescribing and they're overfilling, you got no knowledge of that. Fair?

A Again, I did not do any investigation of Dr. Veres.

14:00:05 **Q** So you have no knowledge of that. Fair?

A Correct.

Q Dr. Torres, same set of questions. Any knowledge about him?

A No difference.

14:00:13 **Q** Dr. Lazzarini, does that ring a bell? Did you ever

hear of him?

A I can't remember any specific information about his case, so no.

Q When he would -- all right. Please keep going.

14:00:28 **A** That's it. I'm finished.

Q When he was sentenced for overwriting prescriptions to prison, he was -- the judge called him Dr. Frankenstein.

Did you hear anything about that?

A That rings some bells, but I don't have any specific

14:00:43 recall of the case.

Q And so did you look to see if the pharmacies in this room were properly filling his prescriptions?

A No, I did not.

Q Did you look at the Ohio Board of Pharmacy statements

14:00:57 on red flags and the responsibility of the pharmacist?

A I have reviewed some of that information in broad terms.

Q Plaintiffs' 21867. Let's see if this is one you reviewed, sir.

14:01:47 Do you have Plaintiffs' 21876 in front of you?

A Yes, I do.

Q State Medical Board of Ohio red flags signs of prescription drug abuse.

Do you see those?

14:01:59 **A** I do see this, yes.

Q The need to look and listen and check.

Did you review this before you testified?

A I have not seen this particular document, no.

Q The red flags that they talk about, you haven't reviewed those as well. Fair?

A That's fair.

Q The National Association of Boards of Pharmacies, which is the collection -- the association of -- the board of pharmacy in each state around the country.

Did you review any of their materials?

A I don't have any specific recall.

Q You don't have any specific recall?

A Correct.

Q Plaintiffs' Exhibit 26403.

Do you have it in front of you?

A Yes, I do, if it's 26403.

Q You know, this is actually a follow-up stakeholder meeting on prescribing and dispensing and it involved not only the National Association of Pharmacies, but the American Medical Association as well.

Do you see that?

MR. MAJORAS: Objection. Can we establish foundation first?

THE COURT: Well, why don't you just ask him if he's seen it or knows anything about it?

BY MR. LANIER:

Q Yeah. Well that's -- that's my question, sir.

Have you seen it? Do you know anything about it?

A I haven't had time to review what this document is.

14:04:06 **Q** I'd like you to look specifically at the PowerPoint that's attached, at least on Page 65, that talks about some legal obligations.

Do you see that, sir?

A Mine goes to Page 46 and then changes to a PowerPoint.

14:04:38 **Q** Yeah. It's the PowerPoint, and it -- go to the PowerPoint now and look at Slide 63 of the PowerPoint. Should have Page 65 in the lower corner.

THE COURT: Doctor, if you want to -- I think I have it. I'll just --

14:04:59 MR. DELINSKY: Your Honor, objection.

Can we go on the headset, Your Honor?

THE COURT: All right.

(Proceedings at sidebar.)

MR. DELINSKY: Your Honor, I believe, and Mr. Lanier will correct me if I'm wrong, but we're going to another reference to the *Holiday*/CVS case in Florida, and we obviously object on 402 and 403 grounds. We understand we've lost 402 --

THE COURT: We're not going to touch *Holiday*.

14:05:31 I think -- if this can be shown or referred to without

mentioning that, he can be -- the doctor can be asked about this statement about, question raised by the red flag was not resolved conclusively prior to dispensing. I assume that's where Mr. Lanier is going.

14:05:50 MR. LANIER: Yeah.

THE COURT: So if you can do it without --

MR. LANIER: Got it.

THE COURT: *Holiday*'s relevant here.

MR. LANIER: Got it.

14:05:55 MR. DELINSKY: Can we mask the top of the page, Mark?

MR. LANIER: Yeah, and trust me, I was trying to do it without going to *Holiday* here, but I do want to say that I did have on my list has he seen the *Holiday* case, 14:06:06 because the *Holiday* case gives a different legal standard than he's giving, and that he never looked at that before he got up here and said what pharmacists should and shouldn't do, I do think is notable.

THE COURT: Well, I'll tell you what, why 14:06:19 don't you -- you're making a point, but I'd rather not have specific references.

MR. LANIER: Got it.

THE COURT: You can ask him if he is, in preparation for his testimony did he look at any legal 14:06:29 actions or any settlements with any other defendants,

period.

MR. LANIER: Okay. I can do that.

THE COURT: And I assume he's going to say no.

MR. LANIER: Okay. Got it, Judge.

14:06:37 MR. DELINSKY: Mark, you'll cover up the top of this page?

MR. LANIER: Yeah. Eric, I probably won't even show it. I'm not trying to mess you guys around. I'm just trying to get to the testimony that I can get to.

14:06:46 Okay?

MR. DELINSKY: All right. Thank you, Mark.

(In open court at 2:06 p.m.)

BY MR. LANIER:

Q Sir, do you have that Slide 63?

14:07:00 **A** Yes, I do.

Q The reference to this slide speaking of the violation of corresponding responsibility in administrative case required delivery of a controlled substance, a red flag was or should have been recognized, and the question raised by

14:07:24 the red flag was not resolved conclusively prior to dispensing, that being held to be a violation of the law.

Were you familiar with it?

A I am not at all familiar with the context of this case. I am familiar with that part of the Controlled

14:07:44 Substance Act, but I'm not familiar with what this refers

to.

Q Suffice it to say, you have not done legal research such that you are able to look at what the law requires on this; right?

14:08:03 **A** I have reviewed -- I'm not an attorney.

Q Good.

A And I have reviewed the Controlled Substance Act in this context, but I can't comment on this individual case, *Holiday*/CVS, what this certain slide is. I just don't have

14:08:19 the context do that.

Q Let's keep moving on, sir. California State Board of Pharmacy.

Did you check what the California State Board of Pharmacy rules were on red flags?

14:08:28 **A** No, I did not.

Q The National Association of Chain Pharmacies, did you check what their national association's rules or comments are on red flags?

A No, I did not.

14:08:40 **Q** The CDC documents on red flags.

Did you look at what the CDC says on red flags?

A No.

Q The settlement agreements that have been entered into by a number of pharmacies around the United States, did you

14:08:56 look into those?

A No.

Q So when you start testifying about what should or shouldn't be done, what's right and proper to do, would you at least agree with me there is a whole lot of limits on your information, your vision?

A I was unable to examine the world of information from the history of pharmaceutical -- pharmacies and interactions with the law, but I spent specific time looking at Mr. Catizone's red flags. We're in agreement about the red flags, but I spent my time focused on the complaint and Catizone's specific red flags.

Q Well, but in that regard, I think you must have failed to read his footnotes and to see all the authority for everything that he said.

Did you cite check him?

A I looked at many of his footnotes and I looked at what he -- what -- some of his supporting material, and I was very underwhelmed.

Q So how could you say you looked at it if you never looked at any of these things which form the bulk of his supporting material?

A The difference in what we looked at in my understanding as a physician is there is no statute that underlines required red flags. There's no regulation that requires specific red flags. We're all in agreement that

red flags are appropriate and good and they're very important prompts to look at prescribing, and that's important, we agree on that. I don't agree with Mr. Catizone's overbroad red flags and how he applies them.

14:10:42 **Q** So you didn't go to law school; right?

A Correct.

Q Has your touches with the law in your life, testifying, whatever it may be, not taught you that there's codified law in a statute, there's law in regulations that's

14:11:04 written down, but there's also law that's established by cases.

Did you know about that?

A I only have a vague knowledge of how that applies to regulations and laws, yes.

14:11:14 **Q** So you don't know, really understand the legal requirements that comes out of cases that have been interpreting the written law.

Is that fair?

A That's fair.

14:11:25 **Q** So if the cases that interpret the law speak of red flags and the obligation to resolve those before you dispense it, brand new to you. Fair?

A I am not familiar with the legal cases. I'm not familiar with that, specifically.

14:11:42 **Q** And if Mr. Catizone cited those and explained that,

and those are explained in his footnotes, those are just footnotes you never went to. Fair?

A That's possible, but I did look at some of his supporting material and still had issues.

14:11:58 **Q** Well, let's add here case law, the law as it's been developed through various cases in court.

You never looked at that, did you?

A I don't remember reviewing specific cases. I do have one pleading on my expert report.

14:12:20 **Q** That's a pleading, though, that's not a judgment or an opinion or a finding. You just looked at a complaint that's been filed in Northern California; right?

A That's correct.

Q All right. Let's move down the road.

14:12:40 I want to now look at the bigger picture with you and then I'll be done. All right?

Let's start with this. You said that the work of the pharmacist should be to make sure a prescription is valid, there's no fraud, no significant drug interactions,

14:13:22 occasionally to see if the information is valid, but not to offer second opinions on the medical treatment; right?

A I'm not sure that states all of my testimony, but I'm not sure what you mean by second opinions.

Q Well, I think your suggestion was that the pharmacist

14:13:38 should not be second-guessing the doctor on the treatment.

But I may be wrong. You tell me. I want to get it right.

Is that the role of the pharmacist in your opinion?

If not, let's make it right. I got a red marker. I'm ready.

14:13:53 **A** So the point that I was making about -- I never remember saying anything about second opinions, is that what I was saying is that the training for pharmacists and physicians is very different, and the physician's in a position with so much more information and background and 14:14:10 materials to make determinations about what's a legitimate prescription. That takes medical judgment. It takes the background and training of a physician. That is not part of the training and experience for a pharmacist, so they would not be able to make those types of determinations -- if it's 14:14:36 a doctor practicing within the standard of care, then the prescription, by definition, would be legitimate.

And Mr. Catizone takes umbrage with that. He doesn't agree with that, specifically in two of his red flags where he doesn't think there should ever been prescriptions for 14:14:56 three medicines of one type or even two medicines, an opioid and a benzodiazapine. And I think those are expressing medical opinions to make -- to call those not legitimate is a medical determination, and I don't agree with that.

Q Okay. So my daughter's just pulled up the daily copy. 14:15:21 This is where I got it from.

Question by Mr. Majoras this morning: Do you look at pharmacists as someone who can give a second opinion on your patients?

No. No. That's not part of their role.

14:15:35 Do you see that?

A I do see that.

Q So can I -- can I erase my red mark through no second opinions, or are you changing your testimony?

MR. MAJORAS: Your Honor, can I have the full

14:15:46 testimony read that Mr. Lanier had up there?

MR. LANIER: Well, I don't have her password.

MR. MAJORAS: Rule of completeness, the question he answered.

THE COURT: Well, all right.

14:15:54 MR. LANIER: I don't care, Judge.

THE COURT: I agree you should read the full sentence or the full answer.

MR. LANIER: And I'm being told it was from yesterday, not today.

14:16:02 No. No. That's not part of their role. They don't have the medical training or diagnostic tools and medical decision-making that physicians have, and so I don't see that as part of their role.

Now, that's my question then, unless you want me to

14:16:19 read more.

MR. MAJORAS: No. I think you cleared it up.

BY MR. LANIER:

Q Now, my question is, can I erase no second opinions because you said that, or are you changing your testimony?

14:16:29 **A** No, they should not have any second medical opinions.

Q Okay.

MR. LANIER: Here you go, Rache.

BY MR. LANIER:

Q So for you, the pharmacist is just supposed to make

14:16:44 sure, hey, is this legitimate, did the doctor write it, does it conflict with another drug. And then occasionally say, you know, is this really your name or something like that; right?

A No.

14:16:56 **Q** I mean, don't you agree that there are doctors who are bad doctors who write bad prescriptions?

A Yes, there are.

Q Don't you agree that there are opioid dispensing doctors that are a serious problem and have been in our

14:17:09 communities?

A Especially in our history, that's true.

Q Don't you agree with me that pharmacists have a role as the last line of defense of keeping these bad doctors' prescriptions from going out on the street?

14:17:22 **A** Pharmacists have a very important role. They always

have the right and professional responsibility to refuse a prescription for any number of reasons. Every pharmacist has that right. They can always refuse it. But when you just -- you blur the picture between second guessing or
14:17:42 maybe trying to do a second opinion on some prescription that may be medically legitimate, that's where we differ.

So the role of a pharmacist is more than what you just outlined here. They also look for allergies, they're important in counseling patients. They do a number of
14:18:01 functions. It's -- and I want them to provide good services and be able to use their professional judgment as to dispensing opioids.

Q You understand they go to like 5 or 6 years of school?

A I understand that.

14:18:16 **Q** You understand they take more pharmacy classes and drug classes than most medical doctors?

A They may do that.

Q You understand that they are the last line of defense at stopping illegitimate doctor prescriptions from going out
14:18:30 on the street?

A They are the last person in the prescription distribution, yes.

Q And that they have a responsibility to make sure that it's not a quack doctor writing quack prescriptions; right?

14:18:44 **A** Their corresponding responsibility states that they

need to monitor physicians, they need to make sure that the prescription is from physicians, licensed physicians that are working in the normal course and usual part of their specialty.

14:19:07 **Q** You understand quack doctors -- that's probably not politically correct.

MR. LANIER: And, Your Honor, I apologize on the record.

BY MR. LANIER:

14:19:14 **Q** But you understand these doctors, these. . . these doctors that are writing prescriptions have valid licenses? You understand that?

A That's correct, but --

Q And you understand that these doctors writing these

14:19:31 prescriptions --

MR. MAJORAS: Your Honor, objection.

MR. LANIER: What's the objection?

MR. MAJORAS: Let him finish with his answer.

THE COURT: Well, I guess you're right. I

14:19:40 guess --

Doctor, you --

I think the doctor had more of an answer.

MR. LANIER: Okay.

THE COURT: Let him finish.

BY MR. LANIER:

Q Okay. I'll reask the question.

You understand they have valid licenses? The answer was yes or no.

14:19:52 **A** My question is yes, but the important thing to consider here in the context of your question is that the enforcement of -- for bad doctors doesn't rest solely on the shoulders of the pharmacist, but rather, that is the function -- in fact, they can't do investigations the way -- 14:20:09 the boards that are supposed to take care of that, they should call the board of pharmacy, they should call the medical board, they should call the DEA, they can even call law enforcement, and those are the organizations that are -- that they're designed to investigate and look at the bad 14:20:28 doctors and get rid of them.

Q Okay. Sir, my question was, you understand that doctors have a valid license? Did you -- can you answer that, please? That's a yes or no.

A It is the responsibility of a pharmacist to check 14:20:40 that, yes.

Q But, no, I said, you understand that these doctors do have a valid license most of the time that are writing these?

A I believe so.

14:20:46 **Q** Okay. And now your testimony, if we take the other

part you were answering that I hadn't asked yet, your testimony is that the pharmacist should go ahead and fill the prescription of the pill mill, just report it to the DEA and let the government take its course, keep filling them, though, the whole time, keep pumping them out and selling them.

Is that your testimony?

MR. MAJORAS: Objection. Misstates testimony.

THE COURT: Sustained.

BY MR. LANIER:

Q Okay. I mean, are you saying that they're supposed to fill these things?

A No, I'm not, I'm saying that --

MR. DELINSKY: Wait. Objection, Your Honor.

MR. LANIER: Well, these are yes/no questions, Judge.

THE COURT: Maybe they are, maybe they aren't, Mr. Lanier.

MR. LANIER: All right.

THE COURT: But you've got to let the doctor finish his answer, however he wants to answer.

MR. LANIER: Okay.

THE WITNESS: Can you repeat the question, please?

BY MR. LANIER:

Q Yes, sir. Let me look it up.

Are you saying that the pharmacists are supposed to fill a prescription from a valid doctor even if they believe it's a pill mill doctor?

14:21:57 **A** I believe that --

Q Yes or no?

A The answer is no, it's not mandatory, but they have to look at each case as individuals. They need to use their judgment.

14:22:05 **Q** Okay. And resolve the red flags; right?

A They need to do their best to resolve every red flag.

Q All right. Couple of true or false questions for you. See if we can get an agreement with me on some of these.

Pharmacies have a role to play in the oversight of

14:22:30 prescriptions for controlled substance and opioid analgesics in particular. True?

A Yes.

Q Pharmacists must evaluate patients to ensure the appropriateness of any controlled substance prescription?

14:22:47 MR. DELINSKY: Objection, Your Honor.

BY MR. LANIER:

Q True?

THE COURT: Overruled.

THE WITNESS: I don't understand what you mean

14:22:58 by appropriateness. Could you be more specific?

BY MR. LANIER:

Q No, just take it in the general sense that you would as a medical doctor.

A I'm not sure how to interpret that because some of that sounds like a second opinion. So if it was Catizone's -- Catizone's red flags, it would be just a slightly elevated dose which the patient may have been getting on a monthly basis for years and would he be -- so who then decides on the appropriateness of that if it's a red flag?

Q So your answer is, I can't answer it. Fair?

A I guess I need more specific information regarding what you mean by appropriateness. Because if it involves medical decision making, no.

Q I'm going to put, can't answer without more info. Fair?

A Yes.

Q All right. Pharmacists have an ethical duty backed by both federal and state law to ensure that a prescription for a controlled substance is appropriate.

MR. DELINSKY: Objection. Objection, Your Honor. Scope.

THE COURT: Overruled.

THE WITNESS: I don't. . . I do believe that pharmacists have an ethical duty to do the best they can to

make sure that a controlled substance is appropriate.

BY MR. LANIER:

Q So just best they can?

A Absolutely. They have to make every best effort.

14:24:39 **Q** All right. Team, if y'all would pass down Plaintiffs' Exhibit 21.

Sir, I took these quotes from a *New England Journal of Medicine* article.

Do you remember read the *New England Journal of* 14:24:57 *Medicine*?

A Occasionally.

Q One of the most premier medical journals in the United States, isn't it?

A Yes, it is.

14:25:03 **Q** In fact, I think it's typically ranked numero uno; right?

A I apologize, I don't know the specific rankings.

Q That's okay. I'm going to show you an article, it's Plaintiffs' Exhibit 21, Abusive Prescribing of Controlled 14:25:18 Substances-a Pharmacy View.

MR. DELINSKY: Your Honor, no foundation's been laid yet.

MR. LANIER: Well, he recognizes the journal.

THE COURT: Overruled. Overruled.

14:25:26 BY MR. LANIER:

Q You recognize the *New England Journal of Medicine* as an authoritative journal, don't you?

A Yes, I do.

Q All right. This is September 2013. Have you ever come across this article before?

A I don't believe so.

Q I want to see if you agree with some of things in it. Let's first make sure we're clear on whose writing it. Mitch Betses, a registered pharmacist, and Troyen Brennan, a medical doctor with a master's in public health.

Have you ever heard of either? Do you know them?

A No, I don't.

Q You'll see their information down below, but I think you'll find that they -- one of them at least, works with -- works for CVS in this case.

Did you know that?

A No.

Q And the CVS-authored perspective here, and the paragraphs after talking about Florida's pain clinics being closed, said, pharmacies have a role to play in the oversight of prescriptions for controlled substances and opioid analgesics in particular.

That was my first statement that you agreed with; right?

A Yes.

Q But you couldn't answer the second without more info, so let's see what info you'd have got if you'd have read it in the journal.

Under the Controlled Substances Act, pharmacists must evaluate patients to ensure the appropriateness of any controlled substance prescription.

Do you see where I read that?

A The context of this article is what I have to note. I want to first note that this is an editorial. It's not a scientifically peer-reviewed article, so this is the opinion of the authors, and I agree that they need to evaluate patients. That certainly is something very agreeable. I'm not sure the context, just the legal definition, how they're scientifically using appropriate. I just don't know exactly that context.

Q So if you had been reading this in the *New England Journal of Medicine* when you came across that you'd say, well, I don't understand that?

A I would read the entire article and I would try to put it in context of what points they're trying to pursue or be persuasive about and try to understand and comprehend the meaning of that after reviewing the whole article.

Q And if you go toward the end, a couple of more things of note in this article. It says, as we noted, pharmacists have an ethical duty, backed by both federal and state law,

to ensure that a prescription for a controlled substance is appropriate. A young person traveling a good distance to fill a prescription and paying cash should raise some concern for the pharmacist.

14:28:38 Do you see that?

A I do see that.

Q If the prescription is valid, the pharmacist might have limited grounds on which to deny medication to someone who might be in pain.

14:28:50 You agree with that, don't you?

A Yes.

Q Yet the DEA has now identified both pharmaceutical distributors and chain pharmacies as part of the problem, encouraging our industry to develop new programs to reduce

14:29:05 inappropriate use.

MR. MAJORAS: Objection to that. Hearsay.

BY MR. LANIER:

Q Did you know about that?

THE COURT: Hold it.

14:29:16 Let's go on the headphones a minute.

(Proceedings at sidebar.)

THE COURT: All right. Mr. Lanier, I thought the point of showing this article was to -- there's specific statements that the authors make. You can ask the witness

14:29:39 does he agree with them, does he disagree with them.

MR. LANIER: That's fine, Judge.

THE COURT: But what the DEA has identified, this isn't something that there's would be an opinion about.

MR. LANIER: That's fine, Judge. I'll put that down. Thank you.

14:29:51

(In open court at 2:30 p.m.)

BY MR. LANIER:

Q Last thing I would note here, article cites Anna Lembke, an article by Dr. Lembke on why doctors prescribe opioids to known opioid abusers.

14:30:17

Did you ever read that article?

A I have not.

Q Okay. Now, I want to talk to you about the trinity prescription.

14:30:48

You remember you've testified about how that can be valid at times?

A Yes.

Q And that's the opioids at issue in this case combined with benzodiazapines combined with muscle relaxants; right?

14:31:05

A Correct.

Q And your example was a spinal cord compression victim who was spasming and depressed followed by cancer victims at end of life; right?

A Yes, I believe so.

14:31:20

Q First of all, can we agree that the spinal cord

compression victim who is spasming and depressed needs to be under constant medical attention if they're going to receive these three?

A Depends on what you mean by constant medical attention, and it also depends on the dosages that we're using. If you use a small enough dose, it may not have significant danger, though, of course, whenever you combine medications there is greater danger. That's where medical judgment comes into play.

14:31:50 **Q** So I looked at your report to try to figure out what your authority was for this. Do you want to tell the jury what your authority is for your opinion that you can do these three all at once and that it's appropriate standard of care?

14:32:07 **A** It's my experience and judgment over 37 years of practice as well as my experience and discussions with other physicians across the country and my continuing medical education and meetings that I go to as well as journal articles and other information.

14:32:24 **Q** Yeah, give me something that's a little more evidence that we can look at that's standard of care in terms of, you know, best practices. Give me an article.

A Best practices is a different subject. We're talking about standard of care.

14:32:40 **Q** Why don't you give me a --

A One of the ways to look at it is to look at Catizone's red flags and then Mr. McCann's disclosure that so many of these trinity prescriptions were out there. And if you assume that most physicians are legitimate and writing legitimate prescription, there's a reason why there's so many in Lake and Trumbull. Not all of those doctors are bad doctors.

Q Sir, I said give me an article. Give me a reference that says it's okay to do it. Jury's already seen many people who are saying it's not. Give us someone who says it is, other than you, at $1,400 an hour.

A I don't have any specific article that you describe.

Q In your report you actually do cite one. You just miscite it. Page 46 of your report.

Despite the increased clinical risk associated with prescribing multiple classes of controlled substances concurrently, prescribers do, in fact, concurrently prescribe an opioid with a muscle relaxant and/or a benzodiazapine in order to provide optimal care to certain patients. CDC acknowledges the legitimacy of this in its 2016 guidance for primary care providers.

Do you see that?

A Yes, I do.

Q And then you say footnote 167, and you cite the CDC guideline from 2016, experts agreed that there are

circumstances where it might -- when it might be appropriate to prescribe opioids to a patient receiving benzodiazapines.

Do you see that?

A Yes.

14:34:38 **Q** What do those three dots mean?

A That there's probably some verbiage between that.

Q Yeah. And you wrote this yourself, didn't you?

A Yes.

Q And this wasn't the guy who did your resume on the

14:34:53 internet, on your website; right?

A That's correct.

Q So we ought to be able to go to that article and find it saying what you say it says, shouldn't we?

A Yes.

14:35:08 **Q** I'm sorry?

A Yes.

Q Okay. That article is demonstrative 68, please, Rachel, if you could pass that out, and Ms. Fleming.

Do you have that in front of you, sir?

14:35:51 **A** Yes, I do.

Q All right. Let's start out with Page 2 -- well, let's first identify it for the jury so they know.

This is the CDC reference that you're citing in your report; correct?

14:36:11 **A** I want to be sure it's in the right periodical. In --

this looks like the CDC guidelines.

Q Here. Let me --

A The citation looks like it may be another MMWR -- yeah, it --

14:36:31 **Q** I'll represent to you that this was given to us by the lawyers that have hired you as supplemental materials that you relied on, if that helps.

A That would help.

Q In other words, I'm not playing gotcha.

14:36:44 **A** Okay.

Q I don't think they are either.

Do you see?

A Yes, I see it.

Q It says, Dowell Haegerich, Chou: Dowell Haegerich, 14:36:56 Chou: CDC Guideline For Prescribing Opioids. That's what it is. 2016.

2016.

Recommendations report and reports.

Recommendations and reports.

14:37:16 **A** I see that, yes.

Q Number 65, Page 1, 1 through 49. And I'm sure since you wrote the report you're recognizing it now, right?

A Well, I definitely recognize the report. It just -- I've looked at it in different context in different versions 14:37:35 of the report because it's been published in many different

formats.

Q Page 2, rationale.

Do you see that, sir?

A Yes.

14:37:50 **Q** This CDC guideline offers clarity on recommendations based on the most recent scientific evidence informed by expert opinion and stakeholder and public input. Scientific research has identified high-risk prescribing practices that have contributed to the overdose epidemic, e.g., high-dose

14:38:15 prescribing, overlapping opioid and benzodiazapine prescriptions, and extended-release, long-acting opioids for acute pain.

Using guidelines to address problematic prescribing has the potential to optimize care and improve patient

14:38:38 safety based on evidence-based practice, as well as reverse the cycle of opioid pain medication misuse that contributes to the overdose epidemic.

Now that's not language you cited in your report, but it's from the source.

14:38:55 Do you see that?

A Yes, I do.

Q If you'll go now to Page 8.

Regarding co-prescription of opioids with benzodiazapines, epidemiologic studies suggest that

14:39:21 concurrent use of benzodiazapines and opioids might put

patients at greater risk for potentially fatal overdose.

Three studies of fatal overdose deaths found evidence of concurrent benzodiazapine use in 31 percent to 61 percent of decedents.

14:39:43 And those are footnotes so you can go check out the references; right?

A Yes.

Q In one of these studies -- 67 -- among decedents who had received an opioid prescription, those whose deaths were

14:39:57 related to opioids were more likely to have obtained opioid from multiple physicians and pharmacies than decedents whose deaths were not related to opioids.

Do you see that?

A Yes.

14:40:09 **Q** Okay. Again, part of the report, but not a part you put into yours. Fair?

A Correct.

Q Page 16. Bullet point 3. Clinicians should avoid prescribing opioids and benzodiazapines concurrently

14:40:40 whenever possible. Clinicians should communicate with others managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazapines and opioid exposure, and coordinate care.

Do you see that?

14:40:58 **A** I do.

Q Now, so that we're keeping this clear, that is a two-drug cocktail, it is opiate plus benzo; right? That's a two-drug cocktail; right?

A Yes.

14:41:29 **Q** But the trinity is a three-drug cocktail, opioids and a benzo and a muscle relaxant; right?

A Yes.

Q And that's what's often referred to as the trinity. Some even call it the holy trinity, though, I won't go

14:41:51 there. All right? You got that?

A Yes.

Q Just so we're on the same page because that becomes important in a minute.

So what we're told in this bullet point in the article

14:42:05 you cite is that this should be avoided whenever possible; right?

A That's correct.

Q Something you did not put in your report, but it's here. True?

14:42:22 **A** Yes.

Q One of the red flags of Carmen Catizone. True?

A Yes.

Q That looks more like a hockey stick.

Let's continue. Concurrent use of opiate pain

14:42:47 medications with other opiate medications, benzos, or heroin

can increase the patient's risk for overdose. True?

A Absolutely.

Q And then we go to Page 17. Look at Point 11. It expands. Clinicians should avoid prescribing opioid pain medication and benzodiazapines concurrently whenever possible. That's Point 11 that we're about to read about.

Do you see that?

Do you see it?

A Yes.

Q So let's be real clear. This is Point 11, the two-drug cocktail; right?

A Yes.

Q I don't want to leave anything out, so I'm going to read a little quicker on stuff that's not really relevant, but let's get through this. Clinical evidence reviewed did not address risks of benzodiazapine co-prescription among patients prescribed opioids. However, the contextual evidence review found evidence in epidemiologic series of concurrent benzo use in large proportions of opioid-related overdose deaths, and a case cohort study found concurrent benzo prescription with opioid prescription to be associated with a near quadrupling of risk for overdose deaths compared with opioid prescription alone.

Now, I read it quickly, but you're tracking with that because you're a medical doctor who's spent his life doing

this; right?

A Yes.

Q Still talking, Point 11, but the two-drug cocktail. True?

14:44:45 **A** Yes.

Q Experts agree that although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazapines, example, severe acute pain in a patient taking long-term, stable low-dose

14:45:05 benzodiazapine therapy, clinicians should avoid prescribing opioids and benzodiazapines concurrently wherever possible.

Do you see that?

A Yes. That's very consistent with my testimony.

Q Well, now we've gotten to your quote, so let's look at

14:45:22 it.

Experts agreed there are circumstances where it might be appropriate to prescribe opioids to a patient receiving benzodiazapines.

Do you see that?

14:45:35 **A** I see that, yes.

Q That's what you've quoted. And those dot dot dots, experts agreed that, what you left out is, although there are circumstances.

Do you see that?

14:45:58 **A** Yes.

Q You just put three dots in there and took out the word "although."

A Correct.

Q Didn't you?

14:46:05 **A** Correct.

Q And if you put the word although in there, all of a sudden you need to say something that's a little different.

Experts agreed that although there are circumstances when it might be appropriate to prescribe opioids to a 14:46:25 patient receiving benzodiazapines, and then look what finishes the sentence, clinicians should avoid prescribing opioids and benzodiazapines concurrently wherever possible?

Do you see that?

A I see it, and I agree with it.

14:46:49 **Q** And yet you left that out as well, didn't you?

A The whole point in my quotation --

Q Answer my question, please, sir, and then you can expound all want, but you left that out, didn't you?

A I left out although, yes.

14:47:05 **Q** No, not just the although, you left out the end of the sentence.

A I left out other parts of the sentence, yes.

Q I mean, understand the end of the sentence is important?

14:47:12 **A** It is important.

Q It was a beautiful day. And then the tornado hit. You want the end of the sentence; right?

A I can't argue with you on that.

Q Yeah. It was the best of times, it was the worst of --

14:47:23

A But I was not able to include the entire --

MR. DELINSKY: Objection, Your Honor.

THE WITNESS: But I was not able to include the entire context of the paper, which was specifically for primary care doctors and managing chronic pain. But I agree, and I think my testimony reflects, the combination of drugs is definitely more dangerous. There's no debate about that.

14:47:35

BY MR. LANIER:

Q Well, sir, I'm going to take you to task a little bit more on this because not only do you not give the full citation down here and you avoid -- you leave out the avoid it whenever possible, but you have put in your title that this is opioids concurrently with muscle relaxants and/or benzos. So you're including and here; correct?

14:47:48

14:48:09

A I see the verbiage that you're referring to, but that specific citation is the or.

Q You don't have an and. You cite -- miscite, I would argue, but you miscite --

MR. MAJORAS: Objection.

14:48:26

MR. LANIER: I'll take it back, Judge.

THE COURT: Overruled.

MR. LANIER: I'll still take it back, Your Honor. I don't want to muddy it.

BY MR. LANIER:

Q Sir, your citation, for right or wrong, that is supposedly for this section, is one that deals with and/or.

Do you see that?

A I'd like to see the rest of the section to make sure what context that's in.

Q What do you mean?

A Well, again, there's more information on there than just that -- those four lines under that category.

Q Oh, you mean on your report?

A Yes, on my report.

Q I was trying to figure out, do you want to read the rest of the article?

A Oh, yeah.

Q You've got a little bit more section, and there's not one citation to anything else, not one journal article. Not one reference. No citation anywhere else.

Do you see that?

A There are other relevant citations within my report regarding the concurrent use of benzodiazapines and opioids together, and that would be in the SARA articles.

Q Well, the other section that I can find is on Page 15 of your report, and here you say, the standard of care for prescribing opioids allow for concurrent prescribing of other medications, including benzos and muscle relaxants.

14:50:07 You see that?

A That's correct.

Q And in all that you've got saying that this is the standard of care, you've one footnote, it's 49.

Do you see that?

14:50:17 **A** I see that.

Q And 49 doesn't anymore say that than the man in the moon, does it?

A So I'm not sure of your question.

Q Yes, sir. My question is, you don't have a medical

14:50:50 support for this standard of care in this paragraph (indicating) either, do you, or section either, do you?

A My basis for making my comments about this include the fact that even the CDC guidelines says that it's possible that there are situations where it may be necessary or

14:51:14 suggested.

It's not frequent, we agree on that. Is it more dangerous? Yes. Wherever you mix medicines, it's more dangerous. And I think I was clear on that. The trinity is even more dangerous than just two medicines, but there can

14:51:30 be circumstances, and the CDC guidelines even allow for

that, where it is possible where you may need to and it's appropriate to do that.

Q Where does the CDC say it? Why do they say it, sir?

This whole section is on the two-drug cocktail that they say avoid wherever possible. But where do they ever say the three-drug cocktail is standard of care?

A Again, the -- it does not specifically relate -- the CDC guidelines don't deal with that specifically.

Q And so when you cite it as a footnote to support it, you're misciting it, aren't you?

A I support the or in my sentence.

Q You put an and in your sentence, sir (indicating). You described both the two and the three-drug cocktail.

Do you see that?

A I do see that.

Q Your report miscites this article, doesn't it?

A I think you're taking that out of context, and I think that --

Q Where?

A Because it does respond to the or. It responds to the or, so I don't know about being argumentative about this, but I think the CDC guidelines show some allowance. Is it suggested? No. My point in this whole section is that there may be circumstances, as in the hospice patients in the SARA article, where -- and just all hospice patients,

84 percent receive both opioids and benzodiazapines. So there are circumstances where it is appropriate, and the CDC guidelines does comment to that.

Q Where, sir, is the and part of your report, the trinity, the three-drug cocktail?

A It was not part of that citation.

Q Do you have any medical citation to substantiate your claim that this is okay other than the citation you put down here that doesn't cover it if you read it?

A I have my years experience and clinical activity and meetings that I've gone to. I do not have any citation.

Q These are the meetings funded by Purdue?

MR. MAJORAS: Objection.

BY MR. LANIER:

Q Right?

THE COURT: Overruled.

THE WITNESS: Some meetings have some funding with Purdue among other pharmaceutical and other device reps and other vendors.

BY MR. LANIER:

Q Now I wanted to talk to you about some of your comments on Carmen Catizone. Okay? You commented that Carmen Catizone is saying that the two-drug cocktail is always wrong.

Do you remember that?

A The term he used in the report was contraindicated.

Q And you said contraindication in medical parlance means should never be used, Page 34 of the transcript today, Line 24.

14:54:45 **A** I can't comment on the pages, but, yes, that's what I said.

Q Well, that's wrong too, isn't it?

A In the context of how he put it in his report, that's what he was saying.

14:55:00 **Q** Have you looked up contraindication in a medical resource to see what it says, medical dictionary or medical resource?

A I have.

Q And there are two kinds of contraindications, one is

14:55:11 an absolute contraindication which makes a particular treatment or procedure absolutely inadvisable. Fair?

A Yes.

Q And the other is a relative contraindication which is a condition that makes a particular treatment possibly

14:55:27 inadvisable. Correct?

A I see the definition there. He did not use any of the descriptors and contraindication by itself in medical training is very clear, you never go there.

Q Well, actually, you say that. Where is your reference

14:55:44 for that? Because I looked up medical resources from

legitimate medical sources on the internet and I get this story.

MR. MAJORAS: Objection to testifying.

BY MR. LANIER:

14:55:55 **Q** Well, let me ask it this way.

THE COURT: Rephrase it, please.

MR. LANIER: I'll rephrase it, Judge.

BY MR. LANIER:

Q Where did you get that from?

14:56:00 **A** I did a Google -- I actually verified it with a Google search on contraindication.

Q Okay. Because now we did practice the same way, do the same thing. Don't look at my password.

All right. So let's do a Google search, contra -- 14:56:26 medical definition of medical contraindication. Why don't we hit that. Boom.

Contraindication. Medical definition by Charles Patrick Davis, M.D., Ph.D.

Do you see that?

14:56:40 **A** Well, you pulled up the same definition that you've looked up already, but there's other definitions that didn't pop up first for me, but just contraindication alone would probably state something a little bit differently, more like the first bullet.

14:56:56 **Q** Well, all I looked up was contraindication of

medical -- here, we'll go back.

A Well, you know how Google works, right?

Q Yes, as a matter of fact, I'm suing them right now.

A And if you've been to that site before, it's going to go right to it again. It's going to be the top responder for your search.

Q Here. Well, let's go to one. Here you want to do this one, NCI Dictionary of Cancer Terms. We need something better. We need a medical dictionary. How about this? MedlinePlus, U.S. National Library of Medicine. That sounds significant. Doesn't it?

A Yes, it does.

Q That's the National Institute's of Health, federal government; right?

A Yes.

Q All right. Contraindication. There are two types of contraindication, relative and absolute. One I've never looked at before says the same thing, doesn't it?

A It does.

Q So when you say contraindication in medical parlance means, I got you 2 to nothing so far on this, don't I?

MR. MAJORAS: Objection, Your Honor.

THE COURT: Overruled.

THE WITNESS: I don't agree with that.

BY MR. LANIER:

Q All right.

A From a physician's point of view, if you don't qualify it with relative, then our experience and training would say that it's absolute. A contraindication means you should never go there. If he had said relative contraindication, I suppose you would say, you shouldn't go there most of the time, but he didn't say relative contraindication, he said contraindication. And if you look up --

Q Relative and half --

A -- more definitions --

Q So you just assumed he meant absolute because you think even though the NIH, the dictionaries, and the MedlinePlus mean contraindication, there are two types, you just jumped to the conclusion that he meant something else.

And you swore under oath to that?

A Yes, I did, and I'm comfortable with that interpretation.

MR. MAJORAS: Objection. Rule of completeness Your Honor. I'd like to have the first line read of what was just shown.

MR. LANIER: I'd be glad to, Judge.

THE COURT: All right. All right.

MR. LANIER: Hold on. It got no trouble with that. Hold on.

THE COURT: Read the first line.

MR. LANIER: A contraindication is a specific situation in which a drug, a procedure, or surgery should not be used because it may be harmful to the person.

You don't disagree with that, do you?

14:59:30 THE WITNESS: No.

BY MR. LANIER:

Q There are two types of contraindications: Relative contraindication means caution should be used when two drugs or procedures are used together. It's acceptable to do so

14:59:43 if the benefits outweigh the risk.

Do you see that?

A I see that.

Q Absolute contraindication means the event or substance could cause a life-threatening situation. A procedure, or

14:59:55 medicine that falls under this category must be avoided.

Do you see that?

A I do.

THE COURT: All right. Mr. Lanier, if we're going to go -- if you're finished with that series of

15:00:17 questions, I think it's a good time to take a break.

MR. LANIER: I am, Your Honor, and I'm almost through with the witness too, but I do lack 15 or 20 minutes probably.

THE COURT: All right, then --

15:00:26 MR. LANIER: Thank you.

THE COURT: All right. Ladies and gentlemen, we will take our usual mid-afternoon recess, 15 minutes. Usual admonitions, and then we'll pick up with more of Dr. Wailes' testimony.

15:00:38 Thank you.

(Jury excused from courtroom at 3:00 p.m.)

THE COURT: Please be seated for a minute. Close the back door, please.

All right. I just want to take a minute. CVS and

15:01:19 Walgreens have --

Oh, Doctor, you can step down. This is a legal issue.

-- have proposed a very long limiting instruction. I assume they've given it to the plaintiffs. I'm not inclined to give that. I am willing to give the following

15:01:36 instruction if CVS and Walgreens wants me to give it.

MR. WEINBERGER: Excuse me, Your Honor. When -- was this transmitted to us?

THE COURT: Well, it was e-mailed to me. I -- it shows Peter and Mark on it.

15:01:49 MR. WEINBERGER: When was it?

THE COURT: Well, 1:03.

MR. LANIER: I've kind of been busy.

THE COURT: So was I, but I checked --

MR. WEINBERGER: 1:03 this morning?

15:01:58 THE COURT: No, no, no. 1:03 this afternoon.

1:03.

MR. WEINBERGER: I turn my phone off when the testimony --

THE COURT: Well, that's fine, but I'm checking because I get case-related stuff, and here was one. All right?

MR. LANIER: I'm going to start e-mailing you while I examine.

THE COURT: Well, to be fair, this was not during the doctor's testimony. It was at 1:03. He didn't start until about 1:10.

MR. WEINBERGER: 7 minutes before.

THE COURT: Right. All right. This is what I'm willing to give it Walgreens and CVS want it.

You heard testimony this morning that CVS and Walgreens engaged Dr. Wailes in opioid litigation involving another government plaintiff. You may consider this testimony only if you find that it bears on Dr. Wailes' credibility. You may not consider the existence of this other litigation as evidence on the merits of plaintiffs' claims.

MR. DELINSKY: We'll discuss over break, Your Honor.

THE COURT: All right. I think that gets to it. It's limited.

The other, I think, went on and on, and this says what you can consider it for and it's not going to the merits.

So if you want to think about that, if you've got better language, fine, but I'm not going to give the long language that the defendants suggested.

MR. STOFFELMAYR: Judge, may I raise one other issue before --

THE COURT: Okay. Go ahead.

[Court reporter clarification.]

MR. STOFFELMAYR: Oh, I'm sorry.

I'd like to raise one other issue before the exam continues after the break. There was a question to Dr. Wailes about --

Am I doing that?

MR. DELINSKY: Do you have your phone in your --

MR. STOFFELMAYR: No, it's turned off.

-- he made a remark about having, you know, reviewed doctors as part of his work on the California Medical Board, and the question was, why didn't they ask you to review Dr. Franklin and all these others. Ms. Sullivan asked essentially the same question of Dr. Alexander, and you had very sharp words for her. So I understood questions like that were completely out of bounds. So I want to make sure we all know what the rules are. You know, why didn't the

lawyers ask you to perform an investigation that you haven't performed.

THE COURT: Well, look, it's been a long trial, Mr. Stoffelmayr. I try to keep the same strike zone for both sides.

MR. LANIER: I don't --

THE COURT: There wasn't an objection here.

MR. STOFFELMAYR: No, I didn't want to -- it wasn't the kind of thing where you want to get up and grind everything to a halt.

MR. WEINBERGER: Are you kidding me?

THE COURT: Well, if you would have -- if you would have objected --

MR. WEINBERGER: There's been so many objections.

THE COURT: Hold it. Hold it. Hold it. If you would have objected, I very well might have sustained it.

MR. STOFFELMAYR: Well, the same thing with Ms. Sullivan. There was no objection at the time and you about had her -- well, you had very sharp words for her at the end of the day when there was a complaint about it.

MR. LANIER: I'll pull it, and if that's way, Your Honor, I'll apologize to the Court and to the opponent. I do not remember this at all.

MR. STOFFELMAYR: I'm not interested in trying to strike the testimony retroactively. I'm just asking that we all be clear on what the rules were.

MR. LANIER: I don't think that that's what --

15:05:04 THE COURT: All right. All right.

MR. LANIER: I will be stunned if that's it, and if so, I will apologize dead up.

THE COURT: Well. . .

MR. LANIER: But I don't think that's it.

15:05:20 THE COURT: The problem is really the way you ask it. It's obviously appropriate to ask a witness if he reviewed anything, but when you say, well, did the lawyers show you this, did the lawyers show you that, that, I don't think, is appropriate. What they chose to review, what they

15:05:37 looked at --

MR. STOFFELMAYR: This was even worse. The question was did they ask you to perform an investigation.

THE COURT: All right. Well, that --

MR. STOFFELMAYR: I'll look at the transcript.

15:05:49 I'm not asking to strike anything. I'm just asking that the rules be fair.

THE COURT: All right. All right. I don't -- I think -- I think that's an improper question, what they asked -- did they ask you to do this, did that ask you to do

15:05:57 that. All right? What you did, what you did. You didn't

do this, you didn't do that, that's fine. But what the lawyers asked you to do isn't -- is -- both sides should stay away from questions like that.

MR. STOFFELMAYR: Thank you, Judge.

15:06:11 THE COURT: And if I was inconsistent, that's on me.

MR. STOFFELMAYR: Well, you weren't because nobody objected. I just wanted to --

THE COURT: All right. Well, I'm glad you --

15:06:17 in my view, that -- no one should be asking questions phrased like that.

MR. LANIER: Judge, I'm looking at the record.

THE COURT: Well, all right. Look, I --

MR. LANIER: It doesn't matter.

15:06:31 THE COURT: Since it wasn't objected to, but in the future, going forward, everyone should be careful about phrasing questions like that.

(Recess was taken from 3:06 p.m. till 3:22 p.m.)

COURTROOM DEPUTY: All rise.

15:22:44 (Jury returned to courtroom.)

THE COURT: Okay. Please be seated. Doctor, you're still under oath.

And, Mr. Lanier, you may continue, please.

MR. LANIER: Your Honor, ladies and gentlemen,

15:23:58 sir, I've reached the end of the road. I'm done. I'll pass

the witness.

THE COURT: I guess we should -- if any of the jurors have any questions, they should give those to Mr. Pitts and I'll show them to the lawyers.

15:24:22 (Brief pause in proceedings.)

MR. MAJORAS: May I proceed, Your Honor?

THE COURT: Yeah, Mr. Joyce.

MR. MAJORAS: Thank you.

REDIRECT EXAMINATION OF ROBERT E. WAILES, M.D.

15:31:55 BY MR. MAJORAS:

Q Good afternoon, Dr. Wailes.

Ladies and gentlemen.

Dr. Wailes, you may not be aware of that this, but in this case Judge Polster has asked the jurors if they have

15:32:04 questions, to write them out. The lawyers can look at them to see what may or may not be appropriate then and make decisions on what to ask.

We have just done that, and I apologize for the delay. I'm going to -- I'm going to read these to you rather than

15:32:16 put them on the screen because sometimes there's multiple parts, and I think I can make these -- to the extent they need any kind of tweaks to them, I can do that for you. So let me just -- in no particular order.

And sir, if you have an answer, please give it. If

15:32:32 you don't, let us know that.

You stated you have some appointments that only take 20 minutes. Are those patients ones to whom you may prescribe opioids?

A Yes. Good question, and thank you for the opportunity to answer questions. I appreciate that.

15:32:48

20 minutes is the briefest office visit that I have. New patients are typically an hour. And so the point that I was making in the context of this is many offices, and really busy offices that have high volume was the question presented to me, see patients literally every 5 or 10 minutes, or 15 even. We are really the exception in that we are not a high-volume practice. The shortest time that we see follow-ups, not new patients, but for follow-ups, the shortest time is 20 minutes. So that was the context of that.

15:33:11

15:33:28

Did that answer the question?

Q Sir, your answer is your answer.

A Okay.

Q I'll go to the next question.

You stated that you counsel patients very extensively prior to prescriptions for opioids. If the patient has a pre-disposed situation, or has the likelihood to become addicted, do you prescribe for long-term use knowing they may probably become addicted?

15:33:36

A Another great question, and a difficult judgment.

15:33:55

You're absolutely right that I have to go through a lot of processes to evaluate to see if a patient is a good candidate for starting an opioid or even continuing an opioid, since many patients come to me on opioids, but it's a similar evaluation. So many different factors go into that. And so there's no yes-or-no answer to that question.

It depends on how great their needs are. It depends how I'm able to monitor them going forward. There are patients that I get that are the highest risk. That is rarely, but occasionally, I get opioid addicts sent to me to help with their pain relief. Those are the ones I'm most cautious about, take the most deliberate care, monitor the very most. But even opioid addicts can have pain. They can have acute pain from an injury. They can have surgery. They still need some pain management needs, and that is possible.

And even the plaintiffs' expert, Dr. Lembke, has agreed on that point in her expert report, that occasionally even people with known opioid misuse or addiction still require some treatment, but boy, do we watch them very, very closely.

Q Following up the examples, and quote, so I believe these are the examples of red flag discussion you had, you may interpret it differently.

The examples you have given are resolutions to red

flags, so can a pharmacist resolve and dispense in those situations; is that right?

A That's correct. The point that I was making in talking about how some of those red flags are easy to dismiss is that they flag too many things. If one fifth of all your prescriptions, 19.4 percent in Mr. Catizone's case, if 1 out of 5 of all your prescriptions are flag -- flagged, you can get alert overdose, if you will. You can get alert fatigue. If there's too many alerts, then you don't pay much attention to it. It's overbroad and captures a lot of things that I talked about inappropriately, because those really -- many of those shouldn't be red flags.

MR. WEINBERGER: Your Honor, can we have a sidebar for a moment, please?

(Proceedings at sidebar.)

MR. WEINBERGER: Your Honor, this is the first witness who takes a question, answers it initially and then proceeds to go off on tangents that have nothing to do with the question and simply reiterates an already stated opinion.

THE COURT: Well, I -- I don't think he went on and on. He answered the question. So let's -- it's what he said before.

MR. WEINBERGER: Well, this isn't an opportunity for him to reiterate --

THE COURT: All right. Look, Mr. Weinberger, Mr. Majoras read the juror's questions, so I just -- I'll just caution just -- tell the witness to just answer the questions succinctly if he can. If he can't, they can't.

15:37:38 MR. MAJORAS: Thank you.

MR. WEINBERGER: Thank you, Judge.

(In open court at 3:37 p.m.)

BY MR. MAJORAS:

Q Dr. Wailes, I've got a number of additional questions that have been written here, and I'll just ask you to as succinctly as possible to respond to the questions being asked. If the lawyers have follow-up, we can do that.

Fair enough?

A Thank you. I apologize. That's not my gift.

Q And just a reminder to you that your answers to these questions, just like the ones the lawyer asks, should be within a reasonable agree of certainty within your profession as a pain management specialist.

Okay?

A Thank you.

Q All right. Next question: A rep -- I think this means a company representative -- a rep comes to your office, buys your staff lunch. The rep presents a product or drug.

Do you, as the doctor, take the word of the rep of the

pros and cons of the product or drug because the rep made it sound great?

A Another good question. I view that as I do all information that comes my way. In medical school we learned to be scientists, and we have to be critical of everything that comes our way because everything has a bias.

What you're describing, someone bring me lunch, and I know they have an agenda and I know they have a product to sell, so the way I would answer that is that as a physician and scientist I try to be very critical of the information I receive and put it and balance it against other information and other sources, so there's always other sources of information to review as well.

Q Next question: Does your clinic have the same header on the prescription pad?

And then there's a follow-up question, so maybe it makes more sense if I read them together.

So do all of the providers in your clinic use the same prescription pad with all of the names on it from your clinic?

A Historically we have. Now we use electronic prescribing, but historically we have had a prescription pad with everyone's name on it.

Q Since when have you been using electronic prescribing?

A We started using some electronic prescribing probably

8 -- 8 years ago, approximately, and we've switched to opioid medical prescribing for the last approximately two years.

Q Next question is, generally with respect to all opioids, what do you suggest a pharmacist do when they feel there are legitimate red flags with a prescription that need to be resolved before they feel comfortable to dispense the opioid prescription, but can't get in contact with the prescriber?

15:40:14 15:40:32 15:40:52 15:41:13 15:41:32

A Great question. That's kind of the crux of the difficulty in this situation. And the pharmacist has to do everything within their power, which means investigating as best they can. And then they have to use their judgment. If they can't get a hold of the doctors, then I think they should use their judgment. They always have the right to not dispense, and there are reasons why they may not want to dispense. There could be good reasons. When they are 1 on 1 with the patient and assess the situation. And my point that I made in my discussion today is that it should be the -- at the discretion, the ultimate decision really should be up to the pharmacist, since they're the last gatekeeper, as to whether to give it or not. If there is that unusual but significant situation where there's no full resolution, he'll need to make a decision.

Q Now, and I think you've answered this in your answer,

you can tell me, but I'll ask the question that's written.

Should the pharmacist still dispense even though he or she can't get in contact with the provider or prescriber?

A And on that I would say it's a case-by-case basis. I'm not going to say blanket yes, because there may be situations where the pharmacist sees the patient and they're intoxicated. That's no good. That's not good.

There may be other examples where the pharmacist uses their professional judgment. So it depends. Again, I want to rely on the pharmacist to use their good judgment and not have just an algorithm or mechanical way to make decisions.

Q Additional questions: The first one relates to PDMPs. Are the PDMPs information all connected no matter what state your prescriptions are prescribed in or dispensed? In other words, can the Ohio -- or can someone, through the Ohio OARRS system, see California information in the CURES system?

A Another great question, and the bottom line is no, someone from OARRS can't see what's in California, and California can't see what's in OARRS here. But OARRS does have a multistate agreement of where they share the similar software platform and can see opiate prescriptions from multiple states.

Q And this is my question: Do you know whether the access among those systems has changed over time?

A It has changed dramatically over time. It's changed tremendously because these systems are relatively new within the last 15 or so years. That's when OARRS started here was in 2006, but it's been improving and more sharing of information over time.

Q Back to my list of questions. If a person is addicted to an opioid, why would another opioid be helpful for their addiction and recovery?

A I was expecting that question. It's a complex issue. The simplest answer that I can provide is that addiction specialists have done lots of research, lots of investigations, and they have found that if they use certain types of long-acting opioids it can reduce the cravings for opioids. That makes sense. But why would you give an opioid to someone who is addicted to it? The explanation for that is they describe harm reduction. That's a term that we use, harm reduction. Because it's a terrible situation. But by using medication assisted treatment, they reduce the deaths, suicide, and overdoses return to addictive behavior profoundly. I can't give you the exact statistic, but it's really significant.

So even though it's not real logical to give someone the same drug, it is effective in reducing or improving outcomes. It's not perfect, but it's better than not using it.

Q How can you measure the level of pain a person may have? Wouldn't it -- or couldn't it just come down to being based on the patient's word?

A Another good question. That's part of the real crux of my specialty is trying to evaluate pain. And we use multiple tools. But it is imperfect.

Firstly, I generally trend to believe patients and their histories. Patients with pain oftentimes suffer from stigma because some of the pain is not obvious. It's not like a broken leg or they don't have a cast on, per se, so it's not always obvious. But you use our measures as well. You look at their behaviors. You get reports from family members. You look at your physical examination. And that's really helpful. You also watch them over time and see how things change, how consistent they are. You try to understand how honest they are in your evaluation. It's a difficult thing, but I think most of the time we get it pretty right.

Q Let me make sure I've got everything.

Okay. Pretty -- very straightforward question.

Did you testify that opioid addiction is all in the head?

A No.

Q Is there any research to find different ways to control pain without the use of opioids?

A Thank goodness, yes, and again, that's a huge part of my specialty, and I've always said the majority of my patients have opioids, but a significant don't get any opioids at all. And we use other medicines, we use other procedures, and the question was about research, yes. We're always looking for, and we do have some better drugs on the forefront that we hope will be useful to replace opioids. So far we haven't got those in clinical use, but we're definitely doing research looking for that.

15:46:58 **Q** What is the difference between oxycodone and OxyContin?

A That's a straightforward question I'm happy to answer.

Oxycodone is a drug and it comes in different formulations.

15:47:12 OxyContin is a brand name for the extended-release formulation. There are other extended-release long-acting oxycodone products, but oxycodone is the name of the drug and OxyContin is a brand of extended-release oxycodone.

Q And next question is, is the use of -- and I'm going

15:47:37 to insert my word -- is the use of prescription opioids over time -- let me start over.

Has the use of prescription opioids over time become less effective?

A I'm going to try to answer that two ways because I'm

15:47:55 not sure exactly where it's coming from, but throughout my

practice it's always been -- opioids have always been good for chronic pain. There's been no change in that. How we prescribed it and how we monitored it and our expertise has increased over the decades I've been working at it.

15:48:16 I think that might be a question that's alluding to tolerance. That's -- if I interpret that question, if you take the same dose for a long time, there is a potential for tolerance, which the medical definition of tolerance is that for the same dose, you get less effective over time.

15:48:33 Luckily in most chronic pain patients, that's not a common occurrence, but it can occur, and it's just something we have to monitor very closely.

Q How long have behavioral and testing -- I'm sorry -- behavioral testing and interventions been in practice with

15:48:53 regard to prescribing opioids to your patients?

A Well, we've had behavioral interventions throughout my entire career, but likewise, that has evolved dramatically in terms of what psychologists and psychiatrists are able to do, both with other medicines besides opioids and other

15:49:20 psychological techniques.

Interventions would talk about the range of other activities besides opioids, which would include all the procedures that we do, and that has advanced dramatically over time. So that has also improved. So luckily, opioids

15:49:38 are not the only choice.

Q Another question about PDMP programs.

What other tools are useful for doctor to -- let me add in a word.

What other tools are useful to identify doctor shopping other than a PDMP program?

A Well, the first thing is always the history and just talking to the patient, and a lot of times there's a simple explanation why there may be someone else on the PDMP who gave them opioids. Sometimes not. But that's what you talk to the patient about. So we actually look at the PDMP before we see the patient, but we don't bring that up. We just ask the patient.

So asking the patient's probably the most valuable source because they're the ones who know the actual history and what they've been through and what to expect in terms of other ways. The PDMP is a good source for that, though.

Q How many times have you prescribed the trinity series of medications in the last 25 years?

A I don't have a number from that -- for that, but I'll be honest with you, it's very rare. I don't use the trinity very much. It's a very uncommon situation. But if I use it even 1 in a hundred times, that 1 in a hundred times, I take very seriously, and I'm very deliberate about what I do with prescriptions. I'm very careful, and I think most responsible doctors would be as well. And so it is rare.

Now, the use of -- I'll leave it at that.

Q How often have pharmacists contacted you regarding trinity prescriptions, when you've made them?

A Not very commonly. Luckily, most pharmacists kind of know the doctors in their area, and I've been there for a long time, so in some ways we have a relationship even though we don't cross paths very much. So it's unusual for me to get calls on the trinity.

Q We're about to the end of these questions.

How many patients that have been treated in your clinic have become addicted?

A Another tough question. I don't have a specific answer for that. It's very rare in your clinic because we monitor them so closely. I know that we don't always pick up every addicted patient, though. Honestly sometimes they fool us or they get around some way, and so I'm sure there's patients that I've treated that have left the practice and have become addicted or are addicted. It's a very low percentage of patients, luckily, again, because we monitor them very carefully for the exact signs and symptoms for addiction.

Q And to the extent you have become aware that patients treated in your clinic have become addicted, are you aware of any who have died in relationship to that addiction?

A No, I'm not aware of any deaths from that.

Q Those are the jurors questions. I have a few of my own. I always hesitate to ask my own after reading so many good ones there.

I'd like to go to just a few things that Mr. Lanier covered with you.

First, do you remember going through Dr. Lembke's CV?

A Briefly, yes.

Q He showed you the various publications and the testifying that she's done.

Do you remember that?

A Yes. Yes, I do remember.

Q Why haven't you written more publications?

A My career has not been in the ivory tower. My pursuit for my -- my calling and my pursuit is to treat patients, and so I don't have a lot of academic credentials, I just don't. And so my desire in my career was to see patients, and it's been very satisfying.

Q Is your answer the same as to why you didn't become a professor or an educator?

A Yes, same answer.

Q Do you have any regrets looking back over the 37 years you've been in practice of the choice you made about doing the work that you've been doing?

A No. I'm very happy with my decision.

Q You also were shown the resume of Mr. Catizone.

Do you remember that?

A Yes, I do.

Q And Mr. Catizone has been -- well, let me ask it this way.

15:54:02 Mr. Lanier pointed out times that Mr. Catizone has testified in various places; right?

A Yes.

Q And other things that Mr. Catizone has accomplished in his career; correct?

15:54:10 **A** Correct.

Q Looking back, again, at your 37 years, any regrets that you have done the practice you have been in rather than being an administrator of an organization?

A I'm very happy with my career and it's trajectory,

15:54:29 yes.

Q Also want to ask you a couple questions that Mr. Lanier asked you concerning Dr. Lembke's publication and as to whether you had read any of them. And do you have a copy of your report with you?

15:54:39 **A** Yes, I do.

Q Now, you actually cite Dr. Lembke a couple of times in your report, don't you?

A Oh, yes. I have read some of other work, but not the works that he quoted.

15:54:50 **Q** And, in fact, in your report, you quote Dr. Lembke;

correct?

A I do quote her in my report, yes.

Q So I'm going to put up on the screen Page 19 of your report, and in particular you can see that I've highlighted the footnote, to the note 59.

15:55:09

A Yes.

Q Now, do you understand that that's the same Dr. Lembke that testified -- or who testified earlier in this case?

A That's what I understand.

15:55:20

Q And in this particular instance you quote her to say that Dr. Lembke conceded elsewhere in 2016 that chronic opioid therapy benefits some patients with chronic pain and that benefit is indicated by improvement in function.

And then you cite an article that she wrote with a

15:55:38

number of other folks; right?

A That's correct.

Q I'm going to ask you to turn to Page 23 of your report, which, again, I also have on the screen, and here you again cite Dr. Lembke, and you write, as written by

15:55:58

Dr. Lembke herself, even in cases where opioid misuse is detected by a prescriber who is treating a patient for chronic pain, opioids do not necessarily need to be discontinued in such cases but rather interventions should be performed to change the patient's behavior.

15:56:16

Do you see that?

A I do see that.

Q And what do you cite as the basis for putting that in your report?

A Her article in footnote 76.

15:56:25 **Q** And that's an article that has Dr. Lembke as the lead author; is that right?

A Yes, that's correct.

THE COURT: If you could take that off the screen.

15:56:49 MR. MAJORAS: Oh. Sorry. Everyone does that.

If I can go back to counsel table, Your Honor. I think I left something there.

THE COURT: Okay.

(Brief pause in proceedings.)

15:57:20 MR. MAJORAS: Thank you, Your Honor.

BY MR. MAJORAS:

Q So, Dr. Wailes, switching gears to a bit, there was a fair amount of discussion with Mr. Lanier about an article or a publication that's cited in one of your resumes.

15:57:35 Do you recall that?

A Yes.

Q And, in fact, Mr. Lanier showed you in the actual article that's cited that you are, in fact, acknowledged -- and I'm putting it up on the stand. This is page -- let me

15:57:56 identify it. Page 284. It's CT3 demo 075.

This is the occipital nerve stimulation study; is that right?

A Yes, it is.

Q And Mr. Lanier showed you in the acknowledgements where you are identified as an investigator who participated in the study; is that right?

A That's correct.

Q And I believe you were even acknowledged earlier in the article; is that right?

15:58:22 **A** That's correct.

Q So let's take a look at what you wrote.

So this is the CV that you were shown P21865, Page 1.

The first part of the reference here is the title of the article; right?

15:58:41 **A** Yes.

Q We go to the second page, here you provide more information about the article; right, at the top?

A That's correct.

Q And you identify very specifically the authors; right?

15:58:58 **A** That's correct.

Q That would be Saper -- I won't list them because I'll mistaken their name and I apologize for that. Let do it this way.

In citing an article typically as an article in a medical journal or publication, are the authors listed

usually in the order in which they participate -- I'm sorry -- the principal authors of that article?

A Typically, yes.

Q So you would assume this article, the principal author, but with help from others, was JR Saper as identified here?

A Yes.

Q Now, in your resume, you say, ONSTIM investigator, and then in boldface you have your name, Robert Wailes; correct?

A Correct.

Q Is that the same Robert Wailes who is the investigator acknowledged in the article?

A Yes.

Q You had some questions about off-label use of medications.

Do you recall those?

A Yes.

Q Please describe -- briefly, if you can -- please describe what it means to prescribe a medication that's off-label.

A The FDA goes through an extensive evaluation of drugs to get FDA approval, and it will typically list specific indications that have been researched and studied and used for that drug. And that is a very long and difficult process. Once a drug is FDA approved, over time it may come

and be utilized for other applications. And I can describe that same situation with many antidepressants that we actually use for pain specifically. I can describe that for seizure medicines that are no longer used for seizure medicines but are used for pain, and many times, if not most, I don't know the percentage of the manufacturers of those drugs don't go through the trouble of getting FDA and FDA indication, because it's not required.

The FDA has already said that it's safe and efficacious for one thing, and you have to be very aware and be cautious if you use it for something else, but you look into the pros and cons -- it's not against the law or against regulation. It's a widely accepted practice for many medicines. You still have to weigh the pros and cons and be very familiar to that drug to make sure that it applies to any other use that you're thinking of.

Q Does the FDA itself provide guidance on off-label use and when it's appropriate?

A I suspect it does, but I can't quote that.

Q Well, let's see if we can.

If he can hand this out to counsel and to Mr. -- Dr. Wailes, please, and the Court.

MR. WEINBERGER: Your Honor, can we go on the headset? Sorry.

(Proceedings at sidebar.)

MR. WEINBERGER: Your Honor, his testimony is clear. He's unaware of whether the FDA has provided guidance for off-label use. They can't just hand him a document --

16:02:40 THE COURT: Well, look, I -- he said I suspect it does, but I can't quote that. I think Mr. Majoras, without putting this on the screen, you can show this to him and say, have you ever read this. All right? If he says no, then that's the end of it. If he says yes, I have read

16:03:01 this, well, then, you can use it. He's a doctor, okay, so --

MR. MAJORAS: I will do that, Your Honor.

I will note, though, that that we've been doing internet searches live with this witness and identifying

16:03:17 information from the FDA website if he knows that is, in fact, what that is and that's a source that relies on. I think it would be appropriate --

THE COURT: He didn't say he relied on it. That's the point.

16:03:27 MR. LANIER: Yeah. That's cross-examination. This is leading by definition.

THE COURT: Well, I will allow -- I will allow you to show it to him without putting them on the screen. If he says he's read or received this in the course of his

16:03:41 practice, well then it's fine. He's been a doctor for

37 years. If he says he hasn't, well, then he hasn't.

MR. MAJORAS: Thank you, Your Honor.

(In open court at 4:03 p.m.)

BY MR. MAJORAS:

16:04:04 **Q** So, Dr. Wailes, without testifying at all about the document in front of you, have you had a chance to look it over as you've sat there at the witness stand?

A I have glanced at it, yes.

Q Have you seen this document, this information from the

16:04:14 FDA before?

A I have not -- I don't have any recall of this specific format, but I have looked at similar type of information from the FDA in the past.

Q And where would -- where does one find as a

16:04:25 practitioner information from the FDA?

A Probably on the FDA website is the easiest place to go.

Q Have you done that yourself?

A I have done that in the past.

16:04:34 MR. MAJORAS: Your Honor, at this point, I'd like to put the document before the witness.

MR. WEINBERGER: Objection.

THE COURT: Sustained.

BY MR. MAJORAS:

16:04:48 **Q** You had some testimony earlier about the ACTIQ

lollipops.

Do you recall that?

A Yes, I do recall.

Q I want to make sure that it -- we understand or the jury understands what a lollipop is in this situation.

Could you explain that, please?

A It's a mode of administration. It's the way the medication comes. It's unusual. It's very unusual. It historically has come in a patch where it's slowly absorbed over three days. Sometimes you get other medicines that comes in pills. Well, this particular formulation comes in a hard kind of sweet lollipop. It's on the end of a stick, and the reason is that it's absorbed very quickly when applied to the inside of your mouth. It's absorbed very quickly, and you can have more quick effects for treating breakthrough pain.

Q Are there particular patients that you would prescribe the lollipop drug that you just talked about?

A Yes.

Q What types?

A The -- some of the examples would be a severe refractory headache that would typically -- that would not respond to anything else and would typically require the patient to go to the emergency room.

And as a last resort, and again, after having tried

many other treatments and techniques, we may consider this. Again, very -- it was very uncommonly used for this type of thing, but it could save a patient a trip to the emergency room by effectively treating a sudden onset of acute headache. That's one example.

16:06:32

There would be other examples of acute onset of pain in patients that are opioid tolerant. You need to typically be on other opioids because this is very potent, but if they have severe breakthrough pain that comes on really suddenly, this potentially is useful for that.

16:06:53

Q Mr. Lanier asked you some questions on your CV, again, about a board certification of the American Academy of Pain Management.

Do you recall that?

16:07:06

A Yes, I do.

Q That's the organization that has gone out of business?

A Yes.

Q Is it at all false that you passed the certification requirements from the American Academy of Pain Management when they were administering it?

16:07:18

A It is not false. It's true that I did pass it.

Q And when they went out of business, did anyone call you and say you're certification is revoked?

MR. WEINBERGER: Objection. That's -- hearsay.

16:07:31

THE COURT: Overruled.

MR. WEINBERGER: Hearsay, Your Honor.

THE WITNESS: No, no one called me --

MR. WEINBERGER: I'll withdraw it.

16:07:38 THE COURT: All right. Hold on a second.

MR. MAJORAS: I can rephrase, Your Honor.

THE COURT: All right. If you'd -- rephrase the question.

By MR. MAJORAS:

16:07:42 **Q** Have you ever received information from anyone that as a result of the American Academy of Pain Management no longer being in business your certification has been revoked?

A No.

16:07:58 **Q** And my last question -- or lawyers are famous or saying last question, so I'll be careful. My last question relates to your discussion on judgment and the use of judgment.

With respect to making judgments about patients for

16:08:15 treatment of care, or for treatment, and prescribing, whose judgment is the most appropriate for making those discussions between a pharmacist and a doctor?

A Well, treatment decisions should be made by physicians.

16:08:33 **Q** And what are those made on, very briefly?

Why is it the physician is in the place to do that?

A Well, one, they're medically -- or legally licensed to do that, and that's part of the scope of practice of a physician by statute and regulation, and the practice of medicine is not included in the statute or regulation for pharmacists. They have different training and background and that would be inappropriate.

MR. MAJORAS: Thank you, Dr. Wailes.

Your Honor, I pass the witness.

Your Honor, may I just approach Mr. Pitts just to hand up the questions?

THE COURT: Yeah.

MR. LANIER: Very, very brief, and then you'll be done, Doctor, I suspect, unless the Judge says otherwise.

RECROSS-EXAMINATION OF ROBERT E. WAILES, M.D.

BY MR. LANIER:

Q We're going to go in reverse order, start at the end and work forward. Okay?

Board certification. American Academy of Pain Management you listed on your resume as something you currently hold; right?

A It is on my resume.

Q Tell jurors when you passed that exam and got it.

A It was a very long time ago, in the early '90s.

Q 30 years ago?

A Could be 30 years. It was early '90s, yeah.

Q And do you think it just lasts forever?

A It depends. When you ask about board certification, some board certification does last forever and there's no way to recertify or process. Other boards, more currently typically have recertification parts to it.

Q Yeah. You've heard the expression of jank, something's jank?

A No, I'm not familiar with that.

Q All right. Normal boards that you're certified by make you reup periodically and still show you're there?

Do you know what I'm talking about?

A I think that the American Board an Anesthesiology is very credible. I think they're part of the American -- I forget the exact initials, but the American association of boards that you quoted that are certified, and they, in fact, don't require recertification for my anesthesiology. So it depends on what board and what the parameters are. It is more current -- the more current you're board-certified, it is more frequent. And like my subspecialty in pain medicine, I do have to recertify on that at least every 10 years.

Q Tell the jury why the organization is gone.

A I told you I haven't been part of that organization for a very long time, so I --

Q Tell them why it's gone.

A I don't know the specifics.

Q Do you know that it was related to all of the opioid issues?

16:11:48 **A** I don't -- no, I don't know any of the specifics about why it went away.

Q Tell the jury how long you think they certify you.

A I'm -- are you referring to the American Academy of Pain Management?

16:12:02 **Q** Yeah. In other words, this -- you say today you're board-certified by them, but they don't exist today. But you passed the test 30 years ago. I mean, wouldn't it be better to say that it's a former board certification? A lot of people list those, you know?

16:12:21 **A** I think that's semantics.

Q Okay.

A I --

Q Next. I want to rely on the pharmacist to use their good judgment and not just have an algorithm or mechanical way to make decisions.

Do you see that?

A I do.

Q Do you understand nobody fusses that point at all?

A Good.

16:12:50 **Q** You understand Mr. Catizone says they need to use

their good judgment, but an algorithm and a mechanical way may show them that there's a red flag that needs to be looked at.

You don't have a problem with that, do you?

16:13:02 **A** It was a long question.

Q Let me back it up and take it apart.

To use an algorithm to help you identify a red flag to look at and decide how to address, nothing wrong with that, is there?

16:13:17 **A** That's correct.

Q To use a mechanical way to make a decision as to whether or not a red flag is present so you could then use your judgment to decide what to do, nothing wrong with that; right?

16:13:31 **A** That -- I agree, that's not -- was not my point.

Q You understand, that's what Carmen Catizone's point is, he's just saying use every tool you've got to identify red flags and then resolve them before you give the drug out.

16:13:47 You don't really have a problem with that, do you?

A I have a problem with Catizone's red flags. I don't think that actually states my interpretation of his red flags.

Q But I went through those red flags of the defendants' and they mirror Carmen Catizone's.

Did you not see that?

MR. MAJORAS: Objection, scope.

MR. DELINSKY: Objection, Your Honor.

THE COURT: Overruled. He can answer the question.

THE WITNESS: So, my interpret -- interpretation is that red flags in general are very good and very important. My specific objections with Mr. Catizone's is that, number one, they're overbroad and capture way too many false positives of appropriate legitimate medical prescribing, so they're not useful in the context that he puts them in. And other objections that I have regarding his is his hard line that he draws by if the red flag cannot be resolved, they should not be dispensed. And I argue that in those cases where they cannot be resolved that it is up to the judgment. They may choose not to dispense, but it should be up to the judgment of the pharmacist. And further, on two of his red flags he is very absolute in his terms about them not being medically legitimate.

BY MR. LANIER:

Q Did you hear my question?

A You could repeat the question to make sure.

MR. DELINSKY: Objection, Your Honor.

THE COURT: Sustained.

BY MR. LANIER:

Q Sir, I asked you when I went through the red flags of the defendants, to some degree, they mirrored Carmen Catizone's red flags, didn't they?

16:15:32 **A** And I was disagreeing with that. To some degree, yes, but I was being clear -- I think your question wanted a simple yes or no when they are similar in many ways, they're both red flags, and I discussed the way that they're different.

16:15:49 **Q** But your fuss is with the application of the red flag, not whether or not it's a red flag; right?

A In essence that's true. Now --

Q Okay.

A -- the specific red flags, again, I don't -- I don't

16:16:02 appreciate at all that they capture 20 percent of all of the legitimate prescriptions, but I'm not arguing about having red flags. I think it's important.

Q And you understand that 20 percent, to just give a good close examination before the drugs go out, these

16:16:21 dangerous drugs that have historically been abused in America to the detriment of our communities, you understand to give a close inspection on those before you send them out is not a bad thing?

MR. DELINSKY: Objection, Your Honor, to the

16:16:36 testimony.

THE COURT: Overruled -- overruled.

THE WITNESS: Yeah. I think it's an obligation of the pharmacist to have close scrutiny of all prescriptions.

16:16:45 BY MR. LANIER:

Q Thank you.

Next subject. You keep saying you spend time in practice, not an ivory tower; right?

A Yes.

16:16:54 **Q** But, I mean, in fairness, you don't spend all your time in practice; right?

A That's correct.

Q Because, I mean, you're like -- you're doing the AAPM board meeting stuff and trustees for decade plus, going to

16:17:05 the dinners, the AMA function, all of that; right?

A I do have many other activities.

Q And you've been dealing with the drug companies on giving speeches on their behalf; right?

MR. MAJORAS: Objection. That misstates

16:17:17 testimony.

MR. LANIER: No. He doesn't remember which ones, but you've done it.

THE COURT: Well --

THE WITNESS: I honestly don't remember --

16:17:22 THE COURT: -- overruled.

THE WITNESS: I honestly don't remember in the last 10 years doing that.

BY MR. LANIER:

Q All right, maybe not the last 10.

16:17:27 **A** Or before that, I don't have any specific recall.

Q Okay. You're spending time testifying, aren't you?

A Yes, I am.

Q This is time away from your practice?

A Yes, it is.

16:17:37 **Q** This is time you could be spent write an article?

A That's possible.

Q You could have spent your time at the meetings for the AAPM writing articles?

A That's possible.

16:17:51 **Q** You could be spending your medical association time writing articles?

A This is true.

Q And when you cite Dr. Lembke as being in an ivory tower, are you being -- some might take that. . . in a kind

16:18:11 of -- as an insult.

You're not insulting her, are you?

A No. I have the highest respect for Dr. Lembke.

Q Okay. And when you say you haven't done it because you've been spending your time treating patients, that

16:18:23 sounds very noble, and I appreciate the fact you're a

medical doctor treating patients, but you find time to do a whole lot of other things professionally, don't you?

A A lot of other things, yes.

Q In fact, the job you're doing right now for 150,000 a year or whatever you're getting out there, you said that's 30 percent of your time, didn't you?

A I'm not sure what context that came in.

Q I thought you said you spend like 30 percent of your time as the president of the CMA?

A Oh, the CMA, this coming year may take 25 to 50 percent of my time, possibly.

Q And that's time you could have spent writing articles or in the pain clinic treating people; right?

A That's correct.

Q And then last thing, on your article and your resume, sir, we started that not only by referencing the article, but I questioned you on your examination under oath in this case?

MR. MAJORAS: Improper impeachment objection.

MR. LANIER: No. I already did this.

THE COURT: Overruled.

BY MR. LANIER:

Q Where you said, I know the Occipital Nerve Simulator Trial For Refractory Headaches in 2007 in '9 did come out for a paper of which I was one of the -- what's that word

you used under oath?

A Co-authors.

Q And that is a false statement under oath, isn't it?

A I still believe there may be another manuscript. I have a specific recall of seeing my name under a long list of authors on a different -- it's not the same heading, it's not the same study. It was not in PubMed, I agree, but I still have a specific recall of seeing my name as a co-author of --

16:19:53

16:20:09

Q Of a publication nobody can find.

MR. LANIER: Pass the witness, Judge. Thank you.

THE COURT: Okay. Doctor, you may be excused. Thank you very much. Have a good trip back.

16:20:25

THE WITNESS: Should I leave all this paperwork here?

THE COURT: Yes, you can leave it all there.

(Witness excused.)

THE COURT: And let's go on the headphones for a second.

16:20:33

(Proceedings at sidebar.)

THE COURT: All right, first is CVS and Walgreens want me to read the limiting instruction that I proposed? This would be the appropriate time.

16:20:53

MR. DELINSKY: Your Honor, we don't at this

point.

THE COURT: Okay.

MR. DELINSKY: We are concerned the instruction doesn't capture it and will simultaneously remind the jury of the issue. We would ask that moving forward, the plaintiffs not repeat that testimony, or repeat that Q and A. It's in the record once. That's fine. But we'd like the prejudice not to be compounded.

THE COURT: Well, it won't be in because, I mean, it -- this had to do with some specific work, current work that Dr. Wailes was hired to do.

MR. DELINSKY: Well, my point is, I'm trusting Mr. Weinberger or Mr. Lanier in closing arguments not to inappropriately advertise the existence of another lawsuit in another place.

MR. LANIER: I'll have a ton more to do in closing argument than that, Your Honor. I give you my word.

THE COURT: All right. I just want to make it clear that -- I mean, I would give this instruction. If the defendants are requesting that I not give it, I certainly won't.

THE DEFENDANT: We don't think it would be helpful at this point in time, Your Honor.

THE COURT: Okay. Then I won't.

MR. DELINSKY: Thank you.

THE COURT: All right. Is there a very short deposition or should we end for the day? What's -- I guess what's next up for the defendants?

MR. DELINSKY: Your Honor, we don't have a very short one. We do have one that runs approximately an hour of deposition time, maybe a little less.

I will tell you for one, it's been a long week and I'm exhausted, and I personally would prefer to stop, but I know I don't have any vote in the matter. But I just --

THE COURT: Well, if it's less than an hour, I think we should have it. I mean, it is what it is. No one has to ask any questions, so I think we should play one. If it's less than an hour, that gets us done around 5:15, 5:20, which is what I was going to end by.

MR. DELINSKY: All right. This is not the most entertaining --

THE COURT: Mr. Delinsky, depositions are never entertaining.

MR. DELINSKY: Okay.

MR. LANIER: I resemble that, Your Honor.

THE COURT: And, in fact -- okay. But. . .

(In open court at 4:33 p.m.)

THE COURT: All right. Ladies and gentlemen, we're going to have one -- one more witness this week by deposition. It's not -- it's not real long, and so we'll be

able to conclude around our normal adjournment time.

MR. DELINSKY: Your Honor, may I introduce the witness briefly?

THE COURT: Sure.

16:23:18 MR. DELINSKY: Good afternoon, ladies and gentlemen of the jury, and my sincere apologies that we have to end a long week with a deposition.

This is another deposition, and I'll give you official title in a sec, but let me just reduce it to lay terms.

16:23:35 This is a deposition of another DEA -- actually, this will be our first Drug Enforcement Administration deponent.

The person who we'll be hearing from is named Stacy Harper-Avilla, and among her responsibilities is the setting of the quotas we previously heard testimony about on the

16:24:02 manufacture of opioids and other drugs, and I believe we heard that from Mr. Rannazzisi.

Let read to you her official title. Ms. Harper-Avilla is the section chief of the United Nations Reporting and Quota Section at the U.S. DEA. She testified on behalf of

16:24:24 the agency on this specific topic of the quotas that DEA sets each year.

And for Your Honor's information and for the jury's unfortunate information, this runs approximately 50 minutes.

Your Honor, for timekeeping purposes, it's 29 and a

16:24:46 half minutes for defendants and 18 and a half minutes for

plaintiffs.

THE COURT: Okay. Thank you, Mr. Delinsky.

DEPOSITION TESTIMONY OF STACY HARPER-AVILLA

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

COURT REPORTER: Do you solemnly swear that the testimony you shall give in the cause now before this Court shall be the truth, the whole truth, and nothing but the truth, so help you God?

16:25:10 **Q** Ms. Avilla, good morning.

A Good morning.

Q Would you just state your full name for the record?

A Stacy Harper-Avilla.

Q And you understand that today you're providing testimony on behalf of the DEA?

A Yes.

THE COURT: I think we need to improve the sound on this, please. Turn it up.

Q Exhibit 1, and this is a notice of deposition. Have you ever seen this document before?

A Yes.

THE COURT: Can we turn the sound up, please?

UNIDENTIFIED SPEAKER: That's better.

THE COURT: Good. Thank you.

16:25:52 **Q** Okay. Let's go ahead and turn to Page 6, and I direct

your attention to topic 13.

It says: Topic 13. Your practices and procedures related to the establishment of opioid procurement quotas and opioid production quotas for prescription opioids.

16:27:07 Are you authorized by the DEA to testify regarding that topic today?

A Yes.

Q And I now direct your attention to topic 14, the basis for opioid procurement quotas and opioid production quotas

16:27:29 for prescriptions from 1995 to 2018.

Are you authorized by the DEA to provide testimony regarding that topic today?

A Yes.

Q If you could turn to Page 9 of that same document.

16:27:45 And look at topic 3, which reads: DEA's establishment quotas for the production of opioids in the United States including aggregate production quotas, individual quotas and procurement quotas, disclosure of quota to registrants communications with registrants regarding quota requests,

16:28:13 and the disposition of quota requests and the relationship between quota, suspicion orders, diversion, and lawful medical scientific or industrial channels or use.

Did I read that correctly?

A Yes.

16:28:30 **Q** And are you authorized by DEA to provide testimony on

that topic today?

A Yes.

Q So when I ask a question, unless I specifically indicate that I'm asking for your personal opinion, I'm going to be asking for the DEA's answer to that question.

Does that make sense?

A Yes.

Q All right. Ms. Avilla, what is your concurrent role at DEA?

A I am the section chief of the United Nations Reporting and Quota Section.

Q So am I correct that you joined the Drug Enforcement Administration in 2008?

A Correct.

Q Okay. And since that time your work has included work on quota-related matters?

A Yes.

Q In your roles as unit chief and now section chief, did you come to have an understanding of the DEA's practices and procedures related to the establishment of quotas?

A Yes.

Q Did that include -- and did your understanding include the procedures and practices specifically related aggregate production quota?

A Yes.

Q And does it also include practices and procedures related to the procurement quota process?

A Yes.

Q And does it also include individual manufacturing quota?

A Yes.

Q In those positions did you also gain an understanding of the basis or the reasons why those quotas were set where they were?

A Yes.

Q And in any given year during your time at DEA, you understood the reasons the quota was set at the level that it was set at. Is that fair?

A Yes.

UNIDENTIFIED SPEAKER: Objection. Vague.

Q Do manufacturers need to request a quota grant before they can produce controlled substances?

A Yes.

Q Okay. Are manufacturers permitted to manufacture any more of a controlled substance than DEA permits through its quota process?

A No.

Q So in your role, are you involved with the consideration and approval of quota requests?

A Yes.

Q Are you required to approve every request?

A No.

Q And that's because the DEA does not -- is not required to approve every request; correct?

16:31:45 **A** Correct.

Q Is there any statute that grants the Drug Enforcement Administration the authority to set quota for controlled substances?

A Yes.

16:31:56 **Q** Okay. Are you familiar with that statute?

A Yes.

Q Okay. And are there any regulations that DEA has promulgated that set forth the process for setting the quota for controlled substances?

16:32:26 **A** Yes.

Q And in your role as unit chief and then section chief, was one of your responsibilities to apply the processes that were described by statute and regulation in determining the amount of quota?

16:32:53 **A** Yes.

Q Are you familiar with the term "segregate production quota"?

A Yes.

Q What does that term mean?

16:33:05 **A** In summary, it is the maximum amount that the United

States actually needs for its domestic needs, for legitimate, medical, scientific research needs, exportation needs, and inventory allowances.

Q Is Drug Enforcement Administration responsible for determining the aggregate production quota?

A Drug Enforcement Administration is the agency that publishes it, but we work in concert with other agencies.

Q Okay. What other agencies do you work with?

A FDA.

Q Okay. Any other agencies?

A When necessary, yes.

Q Okay. What would those other agencies be?

A Those within the bounds of DOJ and HHS.

Q Were there any other agencies or departments with HHS that DEA communicated with on quota issues?

A There would have been SAMSHA at the time probably.

Q Okay. And what is SAMSHA?

A I don't remember the full name.

Q Fair enough. Fair enough.

Do you know, generally speaking, what SAMSHA does?

A Substance abuse and mental health.

Q Would DEA consider the FDA's input when determining the aggregate production quota?

A Yes.

Q Okay. And would DEA consider SAMSHA's input when

determining the agent production quota?

A Yes, whether it was there.

Q Okay. What else would DEA consider when determining the agent production quota?

16:34:46 **A** DEA would also consider the manufacturer's quota applications, changes in marketplace, manufacturer's changes to their processes, export requirements. . . inventory allowances that needed to be done, new indications, removal of indications, changes in FDA approval, or changes in -- yeah, changes in FDA approval.

Q Okay. Between 1995 and 2018, did the DEA consider all those factors when setting quota?

A Yes, that's part of the whole statement.

Q DEA sets aggregate production quotas for each individual class of controlled substances.

Is that fair?

A DEA sets quota for each class of Schedule I or Schedule II controlled substance.

Q Fair enough.

16:36:15 And what do you mean when you say class of controlled substance?

A A class is the basic substance.

Q Would that include things like oxycodone?

A Yes.

16:36:36 **Q** Okay. Hydrocodone?

A Yes.

Q Hydromorphone?

A Yes.

Q Morphine?

16:36:43 **A** Yes.

Q Oxymorphone?

A Yes.

Q What do you understand the term "manufacturing quota" to mean?

16:36:58 **A** It is the quota granted to a bulk manufacture who synthesizes or extracts aggregate -- active pharmaceutical ingredients from either a noncontrolled substance or a plant or from one controlled substance into another.

Q How does DEA determine what manufacturing quotas to

16:37:22 grant?

A For the manufacturing quota, it is built on their customers and their manufacturing processes, as well as inventory allowances and any other FDA notifications that we've received.

16:37:44 **Q** Fair enough.

Would it be legal for a manufacturer to produce more of a controlled substance than permitted by its DEA quota?

A Not to my knowledge, it's not legal.

Q Are you familiar with the term "procurement quota"?

16:38:06 **A** Yes.

Q What is procurement quota?

A Procurement quota is the maximum amount of quota -- of maximum amount of material a manufacturer can obtain.

Q DEA sets the procurement quota for each manufacturer; correct?

A Of a Schedule I or II controlled substance, yes.

Q How does D.A. determine the procurement quota for any given registrant?

A It would be based on their business activity which is individual to the manufacturer.

Q Okay. When you say business activity, what do you mean?

A It is based on the rationale that they provide DEA on the reason why they need quota.

Q Okay. What is -- is it fair to say that one of the purposes of granting procurement quota is to ensure an adequate and uninterrupted supply of medications?

A It is one purpose.

Q So, for example, there would be a specific procurement quota grant to a manufacturer for oxycodone?

A Correct.

Q And that would be separate from any procurement grant for hydrocodone?

A Correct.

Q And DEA would make an assessment about the appropriate

procurement quota for each molecule separately?

A Yes.

Q Were there any years between 1995 and 2018 that DEA did not consider the actual use and need for the material?

16:40:04 **A** It's still a factor.

Q Were there any years in which DEA did not consider known diversion when determining the aggregate production quota?

A It's still a factor.

16:40:21 **Q** And were there any years between 1995 and 2018 in which DEA did not consider known abuse when setting aggregate production quota?

A True abuse lay with the FDA, so it's a factor once again.

16:40:38 **Q** Between 1998 and 2018, did the DEA consider changes in the currently accepted medical use and treatment with the class when considering or setting the aggregate production quota?

A As set forth by FDA, yes.

16:41:04 **Q** Who at DEA was responsible for communicating with the FDA regarding aggregate production quota?

A The DEA sent a letter signed by Mr. Rannazzisi to FDA.

Q Okay.

A Requesting the information.

16:41:30 **Q** On the occasions that Mr. Rannazzisi requested the

information, did FDA respond?

A Yes, in a letter form back.

Q But for all those classes of controlled substances that are FDA approved, DEA considered IMS Health or IQVIA data when setting the aggregate production quota; correct?

A Only for domestic prescription data, yes.

Q And they considered that in every year from at least 2008 to the present; correct?

A Prescription data would be considered as a one point, one single factor in a multifactored system, yes.

Q And it -- did DEA consider data from ARCOS in each year between 1995 and 2018 when determining the aggregate production quota?

A Yes.

Q Did the DEA consider any other estimates of the projected medical, scientific, and reserve stock needs besides the ones provided by FDA when determining aggregate production quota?

A Yes. Those provided by the companies themselves.

Q In addition to estimates provided to DEA of the projected, medical, scientific and reserve stock needs, did DEA come to its own determination of the projected medical scientific and reserve stock need when considering aggregate production quota?

A DEA took into account the manufacturing needs in order

to make those projected accounts from FDA.

Q So in addition to the estimates provided by FDA, the DEA also considered the amounts needed to account for yield or loss in production?

16:44:05 **A** Yes.

Q Is that fair?

Okay. All right. And is it fair to say that under the regulations regarding quota, DEA was responsible for setting quota at a level that was consistent with the

16:44:31 medical, scientific, and industrial needs of the United States?

A Yes. And the reserve stock.

Q When setting the agent production quotas, what data on diversion did the agency use?

16:45:01 **A** Internal data.

Q What sorts of internal data?

A Known quantifiable seizure data, known quantifiable information received from state and local law enforcement agencies or labs.

16:45:24 **Q** And to the extent DEA had data on diversion that was quantifiable, did it consider that data in connection with setting the aggregate production quotas for opioids?

A Yes.

Q And did it consider that data in setting the aggregate

16:45:43 production quota for opioids in each and every year between

1995 and 2018?

A Where it existed, yes.

Q Were there any years during that time period where, to your knowledge, the data did not exist?

16:46:02 **A** There are years where the data was not broken out by controlled substance, so we could not quantify it per controlled substance, and that led to other issues.

Q Okay. Where the data could not be broken out by controlled substance, did the DEA still consider that

16:46:22 information when setting aggregate production quota?

A It could not be attributed to a specific controlled substance, so no.

Q Are you aware of any year between '95 -- 1995 and 2018 in which diversion data regarding oxycodone was not

16:46:52 considered when setting the oxycodone aggregate production quota?

A I am not aware when it was not considered.

Q Are you aware of any year between 1995 and 2018 in which diversion data regarding hydrocodone was not

16:47:16 considered when setting the hydrocodone agent production quota?

A I'm not aware of when it was not considered.

Q Are you aware of any year between 1995 and 2018 in which diversion data regarding any other opioid product was

16:47:40 not considered when setting aggregate production quotas?

A I am not. If it spelled out a controlled substance, then we considered it.

Q And, Ms. Harper-Avilla, have you reviewed this document before?

16:48:17 **A** Yes.

Q And is all the information contained in it accurate?

A Yes.

Q Okay. I'm going to just mark this Exhibit 4.

And just so I understand, this document lists the 16:48:31 individuals at DEA who were required to review and approve aggregate production quota before it was published in the federal register; is that correct?

A Yes.

Q While you were unit chief and then section chief, did 16:48:51 you also have to approve the quota numbers before they were published in the federal register?

A Yes.

Q During any year in which you approved those numbers, did you feel that they did not reflect the legitimate 16:49:13 medical, scientific, and industrial needs of the United States?

A No.

Q I'm going to mark two documents here as Exhibits 7 and 8.

16:49:27 Ms. Harper-Avilla, these are documents that appeared

on DEA's website.

A Okay.

Q Starting with Number 7, which reflects the aggregate production quota history for selected substance between 2000 and 2010.

Do you see that?

A Yes.

Q Okay. Do you recognize this chart?

A I recognize the format of the chart, yes.

Q Okay. And do you agree that it reflects the aggregate production quota history for the substance listed here on the left?

A With the exception of 2010, it reflects the aggregate production quota as finalized from 2000 to 2009.

Q Okay. And with respect to 2010, what does it reflect?

A It would reflect the established.

Q And is it fair to state the established quota might change over the course of the year?

A Correct.

Q Okay. Let's look at Number 8, Exhibit 8.

A Yes.

Q And do you agree that this reflects the aggregate production quota history for the substances listed on the left between the years 2009 through at least 2018?

A The final aggregate production quota, yes.

Q Yes. So just to make sure I'm reading this correctly, if we look in the column 2008, the number is for oxycodone, sale, 70,000.

What does that 70,000 represent?

16:51:24 **A** The 70,000 represents the DEA's estimated final number of the amount of oxycodone for sale that may be required to fulfill legitimate, scientific, medical, research, industrial needs, export, as well as inventory requirements.

Q Okay. And in coming to that number, did DEA take into

16:51:48 account the factors that it was required to consider under the Controlled Substances Act?

A Yes.

Q And in coming to that number, did DEA consider the factors it was required to under the regulation related to

16:52:05 aggregate production quota?

A Yes.

Q And with respect to the numbers listed for the other substances here, did the DEA consider all of the factors it was required to consider under the Controlled Substances Act

16:52:28 in determining those numbers?

A So far as the factors related to that substance, then yes.

Q And just to address the counsel's objection to scope, with respect to all the numbers listed in Exhibits 7 and 8

16:52:48 that are opioids, did the DEA consider all of the factors

that it was required to consider by the Controlled Substances Act?

A Where appropriate, yes.

Q Would you agree that with respect to aggregate production quota for oxycodone, that DEA considered the factors it was legally required to consider?

A Yes.

Q Okay. With respect to hydromorphone, in each of the years listed here, do you agree that with respect to aggregate production quota, DEA considered the factors it was legally required to consider?

A Yes.

Q Now, with respect to hydrocodone, in each of the years listed, do you that with respect to aggregate production quota, DEA considered the factors it was legally required to consider?

A Yes.

Q With respect to oxymorphone, in setting the aggregate production quota in each of the years listed, do you agree that DEA considered the factors it was legally required to consider?

A Yes.

Q With respect to fentanyl, in setting the aggregate production quota for the years listed here, did DEA consider the factors it was legally required to consider?

A Yes.

Q With respect to morphine, in setting the aggregate production quota, did DEA consider all of the factors it was legally required to consider?

16:54:37 **A** Yes.

Q In the numbers that are ultimately published as the aggregate production quota for each of these substance are determined by DEA; correct?

A With assistance from other agencies, yes.

16:54:56 **Q** Does DEA set an aggregate production quota for the total amount of hydrocodone that can be manufactured in a given year?

A Yes.

Q So when hydrocodone is used in a combination product, like Vicodin, the amount of hydrocodone used counts again the quota amount; correct?

A Yes.

Q And that was true when hydrocodone combination products were list as Schedule III controlled substances; correct?

A Yes.

Q Let me -- let me pick up where Mr. O'Connor just left off. He asked you a question referring to Exhibit 7 and 8. He asked you, and I'll just read it right from the record. He said, so just -- just to make sure I'm reading this

correctly, if we look at the column 2008, the number for oxycodone sales, 70,000, what does that 70,000 represent?

And your testimony, ma'am, your answer, that 70,000 represents the DEA's estimated final number of the amount of oxycodone for sale that may be required to fulfill legitimate, scientific, medical research, industrial needs as well as inventory requirements.

Do you remember providing that testimony, ma'am?

A Yes.

16:56:36 **Q** And do -- would your answer be the same for every year reflected on Exhibit 7 and 8?

A It would -- it would be for legitimate medical needs, scientific research, industrial im- -- export, as well as inventory needs, yes, and then the manufacturing losses that

16:57:02 are necessary to make those final figures.

Q Thank you.

And is it also true for every opioid that's listed on Exhibit 7 and 8?

A It would -- it would work for those that are -- have

16:57:17 FDA approved products. Those that do not, no.

Q And which ones have FDA approved products, ma'am?

A That, I can't -- I couldn't cite all of those.

Q Well, oxycodone is one of them; correct?

A Correct.

16:57:29 **Q** Hydrocodone?

A Yes.

Q Hydromorphone?

A Yes.

Q Morphine?

16:57:34 **A** Yes.

Q Fentanyl?

A Yes.

Q Do any others comes to mind after we just reviewed five?

16:57:47 Oxymorphone, for example?

A Correct.

Q And pharmacy chains, such as CVS, Walgreens, Rite Aid, Walmart, Giant Eagle, HBC, they also don't provide any information to DEA that is used to set the quotas; correct?

16:58:03 **A** The list of companies you just provided do not receive quota and therefore are not considered for aggregate production quotas.

Q And DEA does not consult chain pharmacies, such as CVS, Walgreens, Rite Aid, Walmart, Giant Eagle, HBC, when

16:58:20 DEA sets quotas for controlled substances?

A Correct.

Q And pharmacy chains, such as CVS, Walgreens, Rite Aid, Walmart, Giant Eagle, HBC, they also do not apply to DEA for quotas; correct?

16:58:34 **A** Correct.

Q There are a number of statutes and regulations that govern the process DEA must follow and the considerations DEA must consider in establishing quotas for controlled substances?

16:58:47 **A** Correct.

Q Now, DEA endeavors to comply with these statutes and regulations governing the establishment of quotas for controlled substances; correct?

A Correct.

16:59:00 **Q** In following these statutes and regulations, the aggregate production quota reflects the estimated medical, scientific research, and industrial needs of the United States; correct?

A Along with export requirements and inventory

16:59:16 requirements and manufacturing yield and losses counted in, yes.

MR. LANIER: Your Honor, majority of the tender from this point forward is part that we were tendering on behalf of the plaintiffs. I've read ahead and

16:59:35 I'm going to waive the tender of that. So that will conclude the offer.

I've confirmed this with defense counsel, because there's one or two short segments that were their tenders, and we've let Special Master David Cohen know as well that

16:59:50 we're not just delaying the play, we're waiving the play.

THE COURT: Okay.

MR. LANIER: And we'll get new adjusted times to you for time purposes at the right time, Your Honor.

THE COURT: Okay.

16:59:58 MR. LANIER: Thank you.

Thank you, all.

THE COURT: All right.

All right. Ladies and gentlemen, we will recess for the week. Usual admonitions. Again, don't read, review, 17:00:11 listen, encounter anything whatsoever about this case in any form of media or anything remotely connected to this case. No independent research whatsoever.

Do not discuss this case with anyone, and we'll pick up Monday morning at 9:00 a.m. with the next defense 17:00:29 witness, and have a great weekend.

(Jury excused from courtroom at 5:00 p.m.)

THE COURT: Okay. If someone just close the backdoor, please.

Okay. So I guess Monday morning we'll deal with any 17:01:16 exhibits from Dr. Wailes and with the DEA witness.

Special Master Cohen gave me this letter that came from the plaintiffs proposing that I strike the designated deposition testimony for a former Walgreens' employee, Deb Bish, and a former Walmart employee, Debbie Mack, and 17:01:49 for an order compelling the defendants to call these

witnesses to testify live at trial.

I mean, I -- I'm not inclined to do anything like this. I -- I mean, people can call anyone they want. You agreed on the depositions, that's fine.

17:02:11 If the plaintiffs still have time and you want to use rebuttal, you can certainly call these people by video to ask them any additional questions. That's fair rebuttal. So you can call new witnesses or you can call some of the same witnesses. So I guess those two individuals should be

17:02:32 alerted that we may need them not next week, but the following week remotely.

Okay. Anything else anyone wanted to bring up? It's been a long week, but I --

MR. LANIER: Your Honor, Mark Lanier for

17:02:54 plaintiffs.

It would be helpful to know which witnesses are --

THE COURT: All right. I was -- thank you, Mark, I was -- that was the main thing I wanted to ask and I didn't write it down.

17:03:03 So, do the defendants have an idea who they're going to call or play on Monday?

MR. MAJORAS: Your Honor, at this point in time we are juggling still things with --

THE COURT: Understood.

17:03:12 MR. MAJORAS: In part because of Dr. Murphy's

schedule. We will get to plaintiffs, as we typically do, very soon, our disclosures as required under the protocols we have.

THE COURT: Okay. So I know Dr. Murphy is on and there may be others. All right. Well, let the plaintiffs know as soon as you can.

MR. MAJORAS: We will do that, Your Honor.

THE COURT: All right. Anything else?

MR. STOFFELMAYR: Do you have an update just on time?

THE COURT: Yeah, what I -- I basically charged the defendants half an hour for -- it was roughly half an hour for Ms. Avilla and nothing for the plaintiffs because they didn't play anything. So this is what I -- this is what I had for today. Today I had 4.25 for the plaintiffs and 2.25 for the defendants. And so for the week I had, if my math is right, 13.25 for the plaintiffs and 14.75 for the defendants totaling 28. So that's what I had.

MR. MAJORAS: Your Honor, there's still the issue on the Nelson.

THE COURT: Well, I hadn't heard.

MR. MAJORAS: I have a proposal to the plaintiffs. If they tell me yes or no, then that will dictate whether I have to file something with you, Judge, so I've asked. Maybe they know.

THE COURT: All right. On Nelson, the representation was that plaintiffs got 2 hours to question him on documents which had not been timely produced. And Mr. Majoras has represented that a significant number of the documents that plaintiffs questioned Nelson on had, in fact, been produced before his deposition, and if that's the case, then it's appropriate to allocate some of that time. If it was roughly half of them, I'll move an hour -- I mean, I don't -- I don't know. So that's what -- that to me is fair.

MR. MAJORAS: It was two-thirds, Your Honor. I have a specific number I've offered to plaintiffs. If they could tell me, it will save all of us some time.

THE COURT: Again, I don't know, and I don't want to have a long hearing about when these were produced.

MR. LANIER: Judge, we've got it detailed. They fall into three buckets. There are a couple that were just referenced quickly as set-up documents so that it put into context the new documents in light of the old deposition, and obviously those we wouldn't have needed to do if we hadn't had the new documents.

And then there's the new documents.

Then there's a third bucket of documents that evidently were produced right before the deposition, and shame on us, we did not -- in the plethora of documents out

there, we didn't find them beforehand and -- because they were just produced in the weeks before. And so -- as part of the big rolling production.

And so we've tried to negotiate something with Mr. Majoras. I think he's got a proposal in front of Pete and -- Mr. Weinberger, excuse me -- and I think that Mr. Weinberger is in a position to do something with that, but I'm not sure exactly what it is.

17:06:10

THE COURT: I'll let you try and figure this out over the weekend. If not, I'll just -- you know, you give me the -- give me the facts and I'm make a decision. That will be that.

17:06:24

MR. MAJORAS: Thank you, Your Honor.

THE COURT: But I'd rather you work it out. I mean, you look at -- I mean, I --

17:06:34

MR. WEINBERGER: Your Honor, it's not as if we're not prepared to. . .

THE COURT: Understood.

But what I had was that Mr. Nelson was questioned for basically 1.75 hours on -- it was 1.75 by Mr. Lanier. Then Mr. Majoras had half an hour, and Mr. Lanier had another half an hour. So I'm mainly concerned about the first -- the 1.75 that was -- all right. That -- I'm not worried about, you know, cross and rebuttal or redirect, whatever, but we'll focus on that first part and see if you can come

17:06:49

17:07:15

to some agreement.

MR. MAJORAS: We will try to do that, Your Honor.

MR. LANIER: We will work on it, Judge.

17:07:23 Thank you very much.

THE COURT: All right. Have a good weekend. Everyone.

(Proceedings adjourned at 5:07 p.m.)

C E R T I F I C A T E

I certify that the foregoing is a correct transcript of the record of proceedings in the above-entitled matter prepared from my stenotype notes.

/s/ Heather K. Newman *10-29-2021*

HEATHER K. NEWMAN, RMR, CRR DATE